"A RANDOMISED CONTROLLED STUDY TO COMPARE & EVALUATE EFFICACY OF BIOABSORBABLE SUBCUTICULAR DERMAL STAPLER AND VICRYL FOR EXTRAORAL WOUND CLOSURE"

Dissertation submitted to

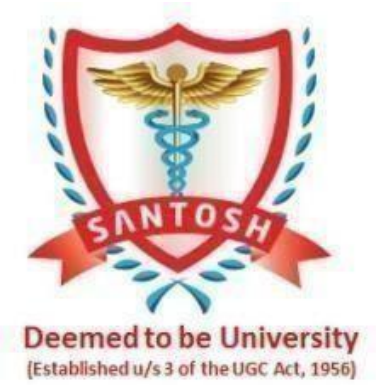
SANTOSH DEEMED TO BE UNIVERSITY, GHAZIABAD, NCR, DELHI

In partial fulfillment of the requirement for the degree of

MASTER OF DENTAL SURGERY

In the speciality of

ORAL AND MAXILLOFACIAL SURGERY



By

Dr. DEEKKSHA BAGHEL

Under the guidance of

Dr. AMIT B. LALL

Professor and Head

DEPARTMENT OF ORAL AND MAXILLOFACIAL SURGERY,

SANTOSH DENTAL COLLEGE AND HOSPITAL

GHAZIABAD-201009, NCR, DELHI, INDIA.

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Dr. Deekksha Baghel

Date:

Place: Ghaziabad

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Date:

Place: Ghaziabad

(Prof.) Dr. Akshay Bhargava
MDS (Prosthodontics)
AFAAID, DICOI, DWCOI

Dean
Santosh Dental College & Hospital
Ghaziabad,NCR, Delhi

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CERTIFICATE BY THE GUIDE

This is to certify that the dissertation **"A RANDOMISED CONTROLLED STUDY TO COMPARE & EVALUATE EFFICACY OF BIOABSORBABLE SUBCUTICULAR DERMAL STAPLER AND VICRYL FOR EXTRAORAL WOUND CLOSURE"** is a bonafide genuine research work carried out by **Dr. Deekksha Baghel** in partial fulfillment of the requirement for the degree of **MASTER OF DENTAL SURGERY** in the speciality of **ORAL AND MAXILLOFACIAL SURGERY.**

Date:

Place: Ghaziabad

GUIDE:
Dr. Amit B. Lall
MDS, DNB
(Professor and Head)
Department of Oral &Maxillofacial Surgery,
Santosh Dental College & Hospital
Ghaziabad, NCR, Delhi

CO-GUIDE:
Dr. Mayank Singhal
MDS, PhD
(Professor)
Department of Oral &Maxillofacial Surgery,
Santosh Dental College & Hospital
Ghaziabad, NCR, Delhi

Deemed to be University
(Established u/s 3 of the UGC Act, 1956)

CERTIFICATE BY HEAD OF THE DEPARTMENT

This is to certify that the dissertation titled **"A RANDOMISED CONTROLLED STUDY TO COMPARE & EVALUATE EFFICACY OF BIOABSORBABLE SUBCUTICULAR DERMAL STAPLER AND VICRYL FOR EXTRAORAL WOUND CLOSURE"** being submitted by **Dr. Deekksha Baghel** in partial fulfillment of regulation for the award of the degree of **MASTER OF DENTAL SURGERY** is based on the bonafide work carried outby her under my direct guidance and supervision and completed to my full satisfaction.

Date:

Place: Ghaziabad

Dr. Amit B. Lall

MDS, DNB
(Professor and Head)
Department of Oral & Maxillofacial Surgery,
Santosh Dental College & Hospital
Ghaziabad, NCR, Delhi

Deemed to be University
(Established u/s 3 of the UGC Act, 1956)

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(Dean Research)

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LIST OF ABBREVIATIONS

S. NO.	ABBREVIATIONS	FULL FORM
1.	SSI	Surgical Site Infection
2.	PDS	Poly-dioxanone
3.	SBSES	Stony Brook Scar Evaluation Scale
4.	RG	Rapid-absorbing gut suture
5.	OC	Octylcyanoacrylate
6.	NL/NYL	Nylon sutures
7.	PGA	Poly-glycolic acid
8.	PLA	Poly-lactic acid
9.	SAS	Subcuticular absorbable staples
10.	MS	Metallic staples
11.	PG	Poly-glyconate sutures
12.	CD	Cadaveric donor
13.	LD	Living donor
14.	CTA	Cyanoacrylate tissue adhesives

INTRODUCTION

Wound closure plays a crucial role in maxillofacial surgery, where the primary goals include functional restoration, infection prevention, optimal healing, and cosmetic outcomes**.** The complex anatomy of the maxillofacial region, which involves soft tissues, bone, and vital neurovascular structures, necessitates precise and effective wound closure techniques to minimize complications and promote uneventful healing. Given the high vascularity of the face and the critical importance of facial aesthetics, appropriate wound closure techniques significantly impact both functional recovery and psychosocial well-being[1]**.**

The overall appearance and integrity of the final scar depends critically on the technique used for wound closure[2]. The commonly used wound closure techniques include sutures, metallic staplers, tissue adhesives and steri-strips. In terms of post-operative pain, patient satisfaction and cost, the evidence regarding methodology to be used is limited[3].

The critical stage of wound healing relies on the stable formation and organization of the newly developed blood clot, ensuring its resilience against mechanical forces. This process involves a complex sequence of cellular and molecular events aimed at restoring the tissue's resistance to functional stress at the wound margins[4].

During wound closure there is implantation of a foreign material in the body which increases the risk of infection at that site. The most bio-compatible materials are associated with low risk of infection and exhibit qualities of being non-porous and chemically inert[5.]

The fundamental characteristics of suture material include knot security, tensile strength, tissue reactivity, and wound stability. In addition to the selected surgical and suturing technique, the choice of suture material can also impact the healing process of the incised soft tissues. Conventional suture materials commonly used include cotton, braided silk, polyester, nylon, and catgut; studies have indicated that polyester sutures elicit a mild inflammatory response, whereas cotton sutures are associated with a more pronounced tissue inflammation[6].

Natural absorbable sutures are derived from biological sources, such as catgut, which is made from purified collagen from bovine or ovine intestines. Degradation of catgut primarily takes place by enzymatic proteolysis, which can lead to unpredictable absorption times due to variations in patient enzyme levels, catgut is also known to cause tissue inflammation. Synthetic absorbable sutures are composed of biodegradable polymers like polyglycolic acid (PGA), polylactic acid (PLA), polydioxanone (PDS), and polyglactin 910 (Vicryl). Degradation of these

materials takes place through hydrolysis, providing more predictable absorption compared to natural sutures.

Vicryl (polyglactin 910) is a widely used synthetic, absorbable suture composed of a copolymer of 90% glycolide and 10% lactide. It is known for its predictable absorption, good tensile strength retention, and minimal tissue reaction. The 3-0 Vicryl suture is a specific gauge (USP size 3-0) that provides an optimal balance between strength and flexibility, making it suitable for various surgical applications. Polyglactin 910 is a braided or monofilament synthetic suture. The braided form is coated with polyglactin and calcium stearate to enhance handling and knot security. Degradation occurs through hydrolysis, where water molecules break down the polymer bonds. This process is more predictable compared to enzymatic degradation seen in natural sutures like catgut. Tensile strength retention for Vicryl is ~75% at 2 weeks, ~50% at 3 weeks, and minimal strength by 4-5 weeks. Complete absorption occurs within 56 to 70 days as the polymer fragments are metabolized and excreted as carbon dioxide and water. It can cause minimal acute inflammation, usually limited to a transient foreign body reaction. Coated Vicryl improves handling and reduces tissue drag, while uncoated versions may have superior knot-holding properties. The major drawback of sutures is the occupational hazard of needle stick injury which poses as a major threat to the surgeons[7].

Tissue adhesives are biomaterials that are specifically engineered to adhere to biological tissues, facilitating wound approximation, hemostasis, and reinforcement of surgical repairs. Tissue adhesives function through distinct physicochemical mechanisms that vary based on their composition and intended use. Their efficacy depends on factors such as polymerization kinetics, tissue biocompatibility, degradation profile, and mechanical strength. The primary categories of tissue adhesives include cyanoacrylate-based adhesives (synthetic), fibrin-based adhesives (biological), polyethylene glycol (PEG)-based adhesives, and albumin-glutaraldehyde adhesives, but they pose a major disadvantage as they lack tensile strength thus cannot be placed in areas of tension[8].

Metallic staplers are commonly used in surgical procedures, particularly in head and neck closure, to approximate wound edges efficiently. These devices provide a rapid, uniform, and secure closure, reducing operative time and minimizing tissue trauma. They are widely utilized in trauma cases, maxillofacial surgeries, thyroidectomies, and reconstructive procedures. It is faster than traditional suturing, reducing operative time and blood loss. Staples ensure even tension across the wound, promoting better healing and minimizes tissue handling, lowering the

chances of wound infection. Disadvantages include requirement of a specialized staple remover, unlike absorbable sutures. It is also known to cause mild irritation or discomfort, particularly in thin skin areas like the neck. Out of all the major cons of using metallic staples is that it can cause scarring, especially in delicate cosmetic areas[9].

Advancements in suture materials and design have significantly broadened their biomedical applications. Recent developments and emerging trends in suture technology holds substantial potential for clinical and surgical applications, particularly in specialized procedures and wound management.

One such advancement is the use of bioabsorbable subcuticular dermal staplers for extraoral wound closure. Absorbable subcuticular dermal staplers represent a significant advancement in wound closure technology, providing an efficient, minimally invasive, and cosmetically favorable alternative to traditional sutures and non-absorbable staples. These devices are designed to approximate wound edges at the dermal level, promoting optimal healing while eliminating the need for staple removal. Their application is particularly beneficial in plastic surgery, orthopedic procedures, laparoscopic incisions, obstetric and gynecologic surgeries where precise wound closure and minimal scarring are paramount but have not been assessed in the maxillofacial region yet. Unlike conventional skin staples, which require manual extraction, absorbable dermal staples are biodegradable and undergo gradual enzymatic or hydrolytic degradation, aligning with the body's natural wound healing process. The use of such devices reduces procedure time, ensures uniform wound tension, minimizes foreign body reactions, and most importantly ensures operator safety thereby improving overall patient outcomes[10].

Wound closure is a crucial step in surgical and traumatic wound management. The choice of method depends on wound type, location, tension, infection risk, and cosmetic outcome**.** The conventional techniques of wound closure had many drawbacks like time-consuming application, higher scarring (hatch marks), needle prick injuries, surgical site infections and need for removal of the suture. Current literature supports the superiority of absorbable subcuticular dermal staplers in comparison to other wound closure modalities in procedures like abdominoplasty, breast augmentation, cesarean section (C-section) closures, laparoscopic surgeries, etc. but there is a lack of studies involving the use of subcuticular dermal staplers in the maxillofacial region[2].

Due to scarcity of literature on the use of bio-resorbable dermal staples in extraoral wound closure in maxillofacial region, we have designed this study to compare and evaluate the efficacy of synthetic bioabsorbable, subcuticular dermal stapler and Vicryl in the field of maxillofacial surgery assessing their ability to yield proper wound healing to produce an esthetic scar[4.]

AIM AND OBJECTIVES:

AIM:

The aim of the study is to compare & evaluate the efficacy of bioabsorbable subcuticular dermal stapler & vicryl for extraoral wound closure.

OBJECTIVES:

Following are the objectives for both the groups :

1. To assess the healing of the skin at incision sites by Stony and Brooks scar assessment scale.
2. To evaluate the time taken for closure of incision sites during surgery
3. To evaluate the ease of handling of the SubQ It! stapler/Vicryl according to the operator's comfort
4. To assess postoperative complication such as infection, swelling or discharge due to SubQ It! stapler/Vicryl and scar formation.

REVIEW OF LITERATURE

Austin PE, Dunn KA, Eily-Cofield K et al (1995)[12] conducted a randomized, blinded, prospective trial on 11 Sprague-Dawley rats weighing 300 to 325 g to determine whether buried, absorbable, subcuticular sutures increase the degree of inflammation in non-contaminated wounds. Four wounds were made on each rat. Two wounds on each were closed with three interrupted buried, absorbable, subcuticular sutures 6-0 polyglactin 910 and running 5-0 nylon skin sutures. The other two wounds were closed with running 5-0 nylon skin sutures alone. On histological examination the results indicated no statistically significant difference in mean total wound score of wounds closed with and without buried, absorbable, subcuticular sutures. They concluded that buried, absorbable, subcuticular sutures do not significantly increase the degree of inflammation in non-contaminated wounds.

Ignatius AA, Claes LE (1996)[10] conducted an animal study to evaluate acute toxicity of two degradable polymers, a 70:30 poly (L-D, L-lactide) (PLDLA) and a 90:10 poly (lactide-co-glycolide) (PLGA), by the agar diffusion test and the filter test with LSl29 mouse fibroblasts. Extracts of the materials prepared in phosphate-buffered saline at 37 and 70°C were assessed for mitochondrial succinate dehydrogenase activity by 3-(4,5-dimethylthiazol-2-yl)-25 diphenyltetrazolium bromide (MTT assay) and the incorporation of 5 bromo-2'-deoxyuridine (BrdU) into DNA of BALB 3T3 cells. From the in vitro results it was suggested that PLDLA and PLGA have satisfactory biocompatibility. High concentrations of the degradation products, however, had a toxic influence on the cell culture systems used.

O'Broin ES, O'Donnell M, O'Donovan D et al (1996)[13] conducted a prospective controlled clinical trial to compare absorbable skin tacks with stainless steel staples. An area of at least 50 cm* was grafted in each patient, half of which was secured with absorbable tacks and half with stainless steel staples. Each patient therefore acted as his/her own control. The presence of infection, haematoma and graft take using a grided cellophane sheet were assessed at one week. Infection and excess scarring at tack sites were assessed at one month. The results indicated that both absorbable skin tacks and stainless steel staple sites showed normal healing. The authors concluded that absorbable skin staples were a reliable method of securing skin grafts.

Samuel PR, Roberts AC, Nigam A (1997)[14] published a preliminary case report where they present their initial experience of a new sterile medical grade cyanoacrylate adhesive (Indermil) in otolaryngeal, head and neck surgery. Thirty-three patients who underwent a

variety of head and neck operations consented to have their skin incisions closed using the adhesive and 10 of those also underwent repair of the tympanic membrane, either as part of tympanoplasty or mastoid surgery were included in this study. The result indicated that all the skin incisions healed by primary intention and there were no wound infections. The authors concluded that tissue adhesives were superior to conventional suture in terms of wound closure.

Simon HK, Zempsky WT, Bruns TB et al (1998)[15] conducted a retrospective analysis of patients from a prospective randomized clinical trial evaluating the effects of initial wound orientation on the cosmetic outcome of facial lacerations repaired with histoacryl blue (HAB), a tissue adhesive vs. conventional suturing. Photographs of the wounds were reviewed and the wounds were categorized as being: Langer (+) (>20 degrees deviated from Langer's Lines). Photo- graphic appearance at follow-up was evaluated using a 100-mm visual analog scale (0 = best, 100 = worst) by two plastic surgeons blinded to the method of repair. The results indicated there was no difference in overall cosmetic appearance of facial wounds closed with HAB vs. conventional suturing. Follow-up appearance was significantly worse for sutured Langer (-) vs. Langer (+) wounds. In contrast, cosmetic appearance of lacerations closed by HAB were comparable between Langer (-) and Langer (+) wounds. They concluded that initial wound orientation had a greater impact on the cosmetic appearance for lacerations closed by suturing compared to HAB. HAB was the preferred method of cutaneous closure for facial lacerations oriented against Langer's Lines.

Singer AJ, Gulla J, Hein M et al (2004)[16] conducted a randomised control trial to compare the cosmetic outcome of facial lacerations closed with a single or double layer of sutures. Sixty-five patients were randomized to single-layer (n=32) or double-layer (n=33) closure. The results indicated that length of single layer closure was shorter than double-layer closure. There were no infections or dehiscences in either group. There were no between-group differences in patient or practitioner visual analogue scale scores. All but one patient had an optimal wound evaluation. Scar width was similar at 90 days. They concluded that single-layer closure of nongaping, minor (3cm) facial lacerations was faster than double-layer closure. Cosmetic outcome and scar width were similar in sutured wounds whether or not deep dermal sutures were used.

Zempsky WT, Parrotti D, Grem C et al (2004)[17] conducted a prospective, randomized controlled trial to compare the short-term complications and long-term cosmetic outcomes of

simple facial lacerations closed with 3M Steri Strip Skin Closures or Dermabond. One hundred children aged 1 to 18 were enrolled. Ninety seven patients had results analyzed. Forty-eight received Steri Strip Skin Closures and 49 received Dermabond. Pain scores on a visual analogue scale were greater for the Steri Strip group than the Dermabond group. At short-term follow-up, there was one wound complication in the Steri Strip group and 7 complications in the Dermabond group. Eighty-nine patients received 2-month evaluation (41 Steri Strip, 45 Dermabond). There was no difference in the mean visual analogue scale cosmesis scores. They finally concluded that Steri Strip Skin Closures and Dermabond provide similar cosmetic outcomes for closure of simple facial lacerations. Steri Strip Skin Closure however presented a low-cost alternative for closure of simple facial lacerations.

Holger JS, Wandersee SC, Hale DB et al (2004)[18] conducted a prospective, randomized study to compare the 9-12 months cosmetic outcome of facial lacerations closed with rapid-absorbing gut suture (RG), octylcyanoacrylate (OC), or nylon suture (NL). One hundred forty-five patients were enrolled. Nine month follow up occurred in 84 patients. The result indicated that no clinically important differences in cosmetic outcome at 9-12 months in patients with facial lacerations closed with RG, OC, or NL. They concluded that the only difference among them was the need of removal for NL, thus according to them RG and OC were slightly superior to NL.

Fick JL, Novo RE, Kirchhof N (2005)[9] conducted a randomised prospective animal study to assess gross and histologic tissue responses of skin incisions closed by use of absorbable subcuticular staples, cutaneous metal staples, and polyglactin 910 suture in pigs. Pigs were randomly allocated to 1 of 3 groups from which tissues were collected after death on postoperative days (PODs) 7, 14, 21, & 42. In each pig, 4 incisions were made; 1 was closed subcuticularly with 3-0 polyglactin 910 suture, 1 was closed with metal staples, and 2 were closed with absorbable subcuticular staples. Incision sites were grossly evaluated every 3 days after closure. At necropsy, incision sites and surrounding tissues were examined histologically; a histopathologic scoring system was used to quantitate healing and tissue response directed against the closure material. The results indicated that absorbable subcuticular staples induced a less severe inflammatory response in the early stages of healing in pigs, compared with other commonly used methods of wound closure. They concluded that use of absorbable staples potentially combines the benefits of subcuticular closure with the speed and precision of staple placement.

Ridgway DM, Mahmood F, Moore L et al (2007)[19] conducted a blinded, randomised, controlled trial to compare cosmetic acceptability of scar and neck mobility after collar line incision for neck surgery. Glue was used in (n=14) and stapler was used in (n= 15), closures were performed for hemithyroidectomy (n= 8 versus 6), sub-total thyroidectomy (n= 2 versus 4), total thyroidectomy (n= 1 versus 4) and parathyroidectomy (n= 3 versus 1). The result included that closure with tissue glue took significantly longer than with staples. Neck mobility scores were comparable at 48 h and 1 month. Cosmetic appearance at 6 weeks was comparable when patient, surgeon and independent assessment was performed. The authors concluded that use of glue for skin closure may increased the duration of surgery whereas acceptable neck mobility and wound cosmesis was achieved by the rapid application of stapled skin closure in cervicotomy incisions.

Lloyd JD, Marque MJ, Kacprowicz RF (2007)[20] gave a narrative review describing various closure techniques used in the emergency care to attain tissue approximation. The authors discussed about sutures and various techniques in which they can be used. Cyanoacrylate glue, adhesive tapes, metal staples and hair apposition technique were materials and techniques reviewed. They concluded that none of the techniques could overcome the drawbacks of conventional closure except for the absorbable staples which were being tested on animals and studies on humans were yet to be performed.

Cross KJ, Teo EH, Wong SL et al (2009)[1] conducted a prospective, randomised, controlled study to evaluate more cost effective method for incisional closure in patients undergoing bilateral breast reconstruction. Eleven patients (22 incisions) were enrolled in this study, comparison was done between standard suture and dermal stapler, wound assessment was done by a blinded plastic surgeon using the 13-point Vancouver scar scale. It was found that closure with dermal stapler was 4 times faster than the standard suture. They concluded that closure using the absorbable dermal stapler could be performed significantly faster than standard suture closure techniques, allowing for more cost-effective incisional closure with equivalent cosmetic results.

Dresner HS, Hilger PA (2009)[2] conducted a study among sixteen patients who underwent endoscopic eye-brow lift &/or rhytidectomy. Each patient had 50% of their temporal and postauricular skin incisions closed with subcuticular staples oversewn with 5-0 plain gut and the remaining 50% closed with percutaneous metal staples. Intraoperative assessment for device handling, bleeding, tension and cosmesis was done. Postoperative incision integrity,

inflammation and cosmesis was assessed. It was observed that subcuticular staples produced better tissue eversion, less erythema and equivalent comfort. They concluded that subcuticular staples represent a safe, comfortable and potentially more rapid alternative to percutaneous staples.

Tellis VA (2009)[21] conducted a retrospective study to evaluate the use of new absorbable subcuticular staple device in renal transplant incision closure. Twenty-six patients (19 CD, seven LD) received transplants during the period reviewed. The results indicated that cosmetic result and patient comfort were superior for subcuticular staple device, but it was more time consuming. Skin staples left in for prolonged periods in transplantation contributed to wound discomfort and serous oozing as well as requiring an additional encounter for removal of staples. They concluded that absorbable subcuticular staples were secure and effective and were preferable to metal staple closures even in renal transplant recipients receiving steroids and sirolimus.

Singh BI, McGarvey C (2010)[22] gave a review on the use of metal staples for closure in surgery. They stated that despite of having faster rate of application the risk of infection was three times higher when staples were used in comparison to sutures. The authors concluded that the superficial wound complication rates are higher for wounds closed with metallic staples than for wounds closed with subcuticular vicryl.

Javed F, Al-Askar M, Almas K et al (2012)[7] conducted a review to assess the tissue reactions to the various suture materials used in oral surgical interventions. Seventeen studies were included. Two studies reported that polyglecaprone 25 had positive effects on wound-healing as compared to silk. Six studies reported that silk elicits more intense tissue inflammatory response and delayed wound healing as compared to other suture materials (including ePTFE, polyglecaprone-25, PGA, and nylon). They found that polyglactin 910 sutures were associated with the development of stitch abscess in one clinical study. Eight studies reported that tissue reactions are minimal with nylon sutures. They concluded that tissue reactions to suture materials used for oral surgical interventions vary depending on the surface properties and bacterial adherence properties of the material.

Nitsche J, Howell C, Howell T et al (2012)[23] conducted a retrospective cohort study to compare the in-hospital analgesic use after cesarean section between patients who underwent skin closure with surgical steel staples and subcuticular absorbable polyglycolic acid staples. Eighty-nine subjects were included in the absorbable staple cohort and 95 were included in

the steel staple group. The results indicated that there was a 1.5-fold decrease in ketorolac use and a trend toward decreased ibuprofen use in the absorbable staple cohort. There was no difference in hydrocodone/acetaminophen use between groups. They concluded that the use of subcuticular absorbable staples for skin closure at the time of cesarean section led to less in-hospital analgesic use, and thereby positively impact a patient's post-operative course.

Duteille F, Rouif M, Alfandari B et al (2013)[3] conducted a multicentre prospective study on 100 patients to compare the use of "Insorb" absorbable staples with absorbable thread for dermal suture. All the patients in the study underwent dermolipectomy (N = 65) or surgery for breast hypertrophy (N = 35). Ninety-five patients were re-examined by the surgeon after 1 year of follow-up to assess scar width, suppleness, inflammation, and hypertrophy. The overall result for the 2 groups was found to be similar. They concluded that the use of "Insorb" staples reduced closure time while ensuring good healing quality.

Feese CA, Johnson S, Jones E et al (2013)[4] conducted a randomised control trial comparing metallic and absorbable staples for closure of a Pfannenstiel incision for caesarean delivery. 100 patients were enrolled in the study, 50 were randomised into the control group (metallic staples) and other 50 were randomised in an experimental group (absorbable staples). Assessment was done using visual analog scale, the results indicated that the application of absorbable staples is more time consuming than metallic staples. They concluded that the postoperative pain was comparable for both devices, the absorbable staple skin closure time and cost was significantly greater than for metallic staples.

Biedrzycki A, Markel MD, Brounts SH (2015)[11] conducted an in vitro randomised animal study to compare the in vitro biomechanical properties of a novel subcuticular stapling device to current methods of abdominal skin closure for equine abdominal surgery. Subcuticular absorbable staples (SAS), metallic staples (MS), polyglyconate suture (PG), and nylon monofilament (NYL) were applied to longitudinally transected portions of equine ventral midline skin. Loads that resulted in an initial failure point and the ultimate failure load were recorded. The results indicated that ultimate failure load for PG and NYL were significantly higher than either MS or SAS. For the suture groups, nearly all failures occurred because of skin pull through whereas all SAS staples failed because of staple fracture. Failure patterns were found to be mixed for MS. They concluded that SAS had the lowest ultimate failure load; however, other measured variables identified characteristics of SAS that were clinically beneficial.

Dennis C, Sethu S, Nayak S et al (2016)[8] performed a review on currently used and emerging suture materials and technology including knotless barbed sutures, antimicrobial sutures, bio-active sutures and smart sutures. They concluded that these newer strategies expand the versatility of sutures from being used as just a physical entity approximating opposing tissues to a more biologically active component enabling delivery of drugs and cells to the desired site with immense application potential in both therapeutics and diagnostics.

Han HH, Kim SY, Lee YJ et al (2016)[24] retrospectively reviewed donor site closure using absorbable dermal staple for deep inferior epigastric artery perforator flaps to evaluate its efficacy and cosmetic outcomes. The study was conducted on 25 patients who were either standard suture controls (group I, n = 15) or received absorbable staples (group II, n = 10). The donor site was evaluated by three plastic surgeons in a blinded manner using the modified Vancouver scar scale 6 months after surgery. The scar assessment scores were found to be low in group II than group I. They concluded that absorbable dermal stapling reduced operating time, compared to that of traditional suturing. In addition, scar quality from absorbable dermal staples was superior to that resulting from traditional sutures.

Imamura K, Adachi K, Sasaki R et al (2016)[25] conducted a multicentre open-label randomised control trial comparing subcuticular sutures with subcuticular staples for skin closure after open abdominal surgery. 401 patients were enrolled, 199 patients were allocated to the subcuticular suture and 202 patients to the subcuticular staple. The results indicated that superficial SSI was seen in 25 of 198 suture patients & 27 of 201 staple patients. They concluded that subcuticular sutures did not increase the occurrence of superficial SSIs following open laprotomies mainly consisting of clean-contaminated surgical procedures.

Vierhout BP, De Korte JD, De Vos B et al (2017)[26] conducted a 4 phased comparative effectiveness trial in patients undergoing infra-inguinal femero-popliteal bypass operation. They compared closure of the skin by means of absorbable stapler with a cohort of patients treated with intracutaneous sutures. 44 patients were enrolled in the study; 6 patients underwent skin closure with the absorbable staples and 38 patients underwent skin closure by intracutaneous sutures. SSI was seen in 4 out of 6 staple patients and in 7 out of 38 suture patients They concluded that the absorbable staples were not strong enough for wound closure in peripheral vascular surgery, due to a large proportion of SSIs in the absorbable stapler group the use of these subcuticular staples was discontinued.

Jones CD, Ho W, Samy M et al (2017)[27] gave a review of literature on paediatric and adult human studies that compared octyl-2-cyanoacrylate with conventional closure techniques in a variety of wounds. They found and summarized 17 studies comparing octyl-2-cyanoacrylate skin glue to conventional methods of skin closure. They concluded that Octyl-2-cyanoacrylate skin adhesive produces similar cosmetic results to sutures and other current wound closure techniques while being cost effective, quick and easy to use. Studies suggested that it was a preferable alternative to sutures.

Madsen AM, Dow ML, Lohse CM et al (2019)[28] conducted a prospective, randomized, non -blinded, parallel -group trial to compare outcomes of efficiency, safety, patient and surgeon satisfaction between absorbable subcuticular staples and subcuticular suture for caesarean section skin closure. Of 220 randomized patients, 206 were included in the final analysis (103 per group). Baseline characteristics were similar. The primary outcome of total operative time was not significantly different between groups. The results indicated that subcuticular staple group had shorter subcuticular skin closure time. They concluded that for caesarean section skin closure, absorbable subcuticular staples did not result in significantly different total operative times compared to suture. Analgesic use, wound complications, and cosmesis were comparable. Patient and surgeon satisfaction were high with both methods.

Byrne M, Aly A (2019)[29] described the selection of various suture materials available today and their intended design. They described how modern suture material should have predictable tensile strength, good handling, secure knot-tying properties, and could be enhanced with an antibacterial agent to resist infection. They concluded that monofilament suture has lower resistance when passed through tissue whereas multifilament sutures possesses higher tensile strength and flexibility but greater tissue friction and pose risks of suture sinus and infection. Natural absorbable sutures derived from mammalian collagen undergo enzymatic degradation whereas synthetic polymers undergo hydrolysis. Collagen or polymer structures in the suture can be modified to control absorption time. In contrast, nonabsorbable sutures typically cause an inflammatory reaction that eventually encapsulates by fibrous tissue formation. Excess reaction leads to chronic inflammation, suboptimal scarring, or suture extrusion. More recently, barbed sutures transformed the way surgeons approximate wounds by eliminating knots, distributing wound tension, and increasing efficiency of closure. Similarly, modern skin adhesives function both as wound closure devices as well as an occlusive dressing.

Lalhmangaihzuali PC, Latha BD, More N et al (2019)[30] provided a narrative review describing the current wound closure techniques like sutures, staplers, surgical strips and glues and emergence of absorbable subcuticular staples for faster and effective wound healing management. They concluded that the surgical staplers are fast and easy to use wound closure devices, which approximate the edges of the wounds together by staples. The staples are mostly made up of metals like titanium and stainless steel. By modifying the existing stapling method using biodegradable staples that are expected to have good mechanical properties, do not require removal procedure, minimized scarring and an overall acceleration in wound healing with minimal complications.

Anand BB, Vikram J, Ramesh BS et al (2019)[31] conducted a 2-year prospective randomized controlled study to compare tissue glue, staplers and sutures in primary wound closures following elective surgeries. A total of 90 healthy patients were included in the study where authors compared all the three techniques in terms of time efficacy, post-operative pain, wound complications, cosmesis and cost-effectiveness. The results indicated that staples consumed less time for application when compared to glue and sutures. Glue gave best results in terms of less post-operative pain. The wound ASEPSIS score calculated on 3rd, 5th, and 7th day. Cosmesis score on 7th day, 1st month and 5th month was calculated using modified hollander and VAS cosmesis scale. Cost of material including length of hospital stay for glue was also effective. They concluded that staples application is faster, consumes less significant time than glue and sutures. Skin glue gives the best results in terms of less post-operative pain, wound asepsis, better cosmesis and cost-effectiveness. The concept of tissue glue is a safe, attractive, and effective alternate over other conventional methods of wound closures following elective surgeries.

Hari KM, Kumar HRS, Rai KK et al (2021)[5] conducted a prospective study for evaluation of outcome of the use of bioresorbable subcuticular dermal staples for closure of head and neck skin incisions. The study consisted of 12 patients who underwent surgical procedures requiring extraoral incisions in head and neck region, 9 patients underwent neck dissection and 3 underwent submandibular incisions. Post-operatively, the scar was objectively assessed using Modified Vancouver scar scale for 6 months along with patient satisfaction. The scar assessment scores were found to be decreasing with every postoperative visit and ‘P’ value was statistically significant. They concluded that the absorbable subcuticular staples have the capacity to potentiate wound closure even in high tension regions, although it has to be reinforced by the subcutaneous sutures in such areas.

Taysi AE, Ercal P, Sismanoglu S et al (2021)[6] conducted an in vitro study to evaluate the tensile strength and elongation to failure of commonly used suture materials in oral surgery. Eight different suture materials with 3-0 gauge (silk, polytetrafluoroethylene, polypropylene, polyester, polyglactin 910, polyglycolic acid, poliglecaprone 25, polydioxanone) underwent tensile testing for maximum load of failure and elongation rate. Prepared specimens were examined using a microtensile testing device before (baseline) and after 3, 7, and 14 days' immersion in artificial saliva. Results revealed that the tensile strength for polyglycolic acid, polyglactin 910, polypropylene, and silk sutures was significantly lower at day 3 than at the baseline. By day 14, polyglycolic acid and polyglactin 910 showed a significant reduction in tensile strength for both techniques. While polydioxanone obtained the highest tensile strength and elongation values in both techniques, polytetrafluoroethylene showed the most stable tensile strength even with the lowest value. They concluded that polyglycolic acid and polyglactin 910 were considerably sensitive to immersion time. Polydioxanone demonstrated optimum performance during each immersion period among the tested materials, whereas polytetrafluoroethylene was the most stable.

Patel V, Green JL, Christopher AN et al (2021)[32] conducted a retrospective review comparing patient demographics, operative information, clinical and aesthetic outcomes, and QoL between patients that had INSORB stapler-assisted and suture-only closures. Seventy-five patients were included in the study, with 34 patients in the stapler cohort and rest in suture group. The results indicated that procedure time was significantly less with the use of the dermal stapler. The incidence of major complications was similar between cohorts, as was the incidence of minor complications. No difference in the cosmetic appearance of both the groups was observed. They concluded that the dermal stapler improves efficiency of closure during reduction mammoplasty without increasing the incidence of wound healing complications.

Ashraf I, Butt E, Veitch D et al (2021)[33] performed a retrospective review to summarise the latest evidence relating to suture materials and wound closure techniques, considering the following areas: scar/cosmesis, pain, patient satisfaction, cost, infection, and wound complications. Evidence favoured the use of absorbable sutures with regards to pain, patient preference and cost. Subcuticular sutures were regarded superior to simple interrupted sutures with respect to cosmetic outcome and patient satisfaction. They concluded that subcuticular suture placement was more time-consuming. Skin staples are cost-effective, require minimal skill, and may have similar healing times and infection rates as sutures.

Butt E, Ashraf I, Veitch D et al (2021)[34] performed a retrospective review assessing the evidence for different types of buried suture including braided versus monofilament sutures, longer-absorbing sutures and antibacterial sutures. The majority of trials were noted to be of poor quality, single-centre (thus lacking external validity) and underpowered, which presented challenges in comparing suture techniques in skin surgery. They concluded that low-quality evidence suggested that wound closure with longer-absorbing sutures on high tension sites reduced scar spread.

Singhal S, Taylor KO, Bloom R (2022)[35] conducted a study to evaluate the learning curve of an absorbable subcuticular stapling device in plastic and reconstructive surgery. The study included sixty-six patients who underwent cosmetic procedure corresponding to 254 unique linear incisions. Subdermal closure was done either with interrupted 3-0 monocryl sutures or with "Insorb" device. The results indicated a mild learning curve with the assistant's use of "Insorb". They concluded that in addition to improved speed, cost, outcome, and ergonomics, subdermal absorbable staples garner a faster learning curve than standard closure with 3-0 monocryl.

Komal A, Uzair A, Omer J et al (2022)[36] conducted a single blinded, prospective clinical study to compare skin staples with prolene for closure of neck dissection incisions in terms of time for wound closure, pain on removal and aesthetic outcome. Total 140 patients were enrolled in the study with 70 patients in each group. Incision in group A was closed with 3/0 vicryl and 5-0 prolene while incision in group B was closed using 3-0 vicryl and stainless-steel staples. The results were statistically significant in terms of time of placement while they were statistically insignificant in terms of pain on removal and aesthetic outcome. They concluded that staples are a better modality for closing neck incisions after neck dissection as they are quicker to apply and yield similar outcomes as sutures.

Pandey ND, Singh AK, Choudhary AK et al (2022)[37] conducted a double-blind clinical study to evaluate the efficacy of skin staples and 4-0 prolene conventional suture in closure of extraoral surgical wounds in neck region in elective maxillofacial surgery. The study was conducted on a total of 60 patients, who were equally divided into three groups. In Group 1, wound closure was done using skin staples; in Group 2, wound closure was done using 4-0 prolene suture, and in Group 3, wound closure was done using both skin staples and 4-0 prolene suture. These groups were compared in terms of rate of wound closure; early postoperative pain; pain on the removal of staple and suture; rate of removal of staple and

suture; scar evaluation by the clinician, patient, and two-blind observers on 15th day, 1 month, 3 months, and 6 months. The results indicated that the rate of closure was significantly faster in staple group than in suture group. There was no significant difference in the postoperative pain, pain on removal and rate of removal between the two methods of closure. They concluded that the staple method of wound closure appears to be better than conventional suture in terms of rate of closure and scar appearance.

Mastud K, Lamture Y, Nagtode T et al (2022)[38] gave a narrative review from 17 articles to provide an overview of the critical characteristics of traditional sutures, common suture materials, sticky glue, and staples, as well as additional closure materials. The results indicated between adhesive skin glue, skin staples, and sutures, the glue group appears to have superior post-operative pain tolerance, fewer wound complications, shorter hospital stays following surgery, and better cosmetic results overall. However, there was a lengthier application period than staples and a little greater cost than with sutures. Using sticky glue speeds up skin closure and reduces the length of the surgical procedure. It produces a flexible, water resistant skin closure and improves the appearance. They concluded that because of its additional virtue of being bacteriostatic and the lack of a post-operative removal necessity, skin glue surpasses to be the closure method of choice for the desired wound.

Chandra RB, Selvarasu K, Menon VD (2023)[39] conducted a randomised control trial study to assess cosmetic outcome of various suture materials in extraoral maxillofacial incisions including thirty participants with clinical and radiographic diagnosis of facial fractures, bone pathologies, facial lacerations, abrasions who require procedures like open reduction and internal fixation, maxillectomy or simple closure of the wound. Modified hollender wound cosmesis scale was used for comparison. The results indicated that wound healing index between 2 groups after 1 week and after 1 month were slightly different and concluded that prolene was better than ethilon in outcomes.

Yang N, Venezuela J, Allavena R et al (2023)[40] conducted an in vivo and in vitro study to assess the action of zinc based absorbable subcuticular staples. The fixation properties of the Zn SAS were measured by the authors via pull-out tests and in-situ lap-shear pull out test comparatively against the PLGA SAS. The results indicated that Zn SAS exhibited fixation force three times higher than that of PLGA SAS. The authors used Zn SAS to close incision wounds in a SD rat model for biodegradability and biocompatibility characterisation at 1, 4 and 12 weeks. The results indicated that Zn SAS showed uniform degradation behaviour after

in vivo implantation at the 1, 4, and 12 weeks, which caused a reduction in the fixation force. They concluded that the slow long-term degradation rate of the Zn SAS can lead to unnecessary implant retention. In addition, the alloy SAS can result in higher local foreign body responses due to their stiffness.

Charoenlux P, Utoomprurkporn N, Seresirikachorn K (2023)[41] conducted randomized controlled trials comparing CTAs versus sutures for skin closure on the face and neck were included. Primary outcomes were cosmetic outcomes. Secondary outcomes were scar depth, scar width, pain, closure time, cost, and adverse events. Subgroup analyses were performed by wound locations, type of CTAs, type of sutures, age groups, and type of wounds. Physicians and patients evaluated the cosmetic outcomes. Subgroup analyses revealed no differences. CTAs offered less scar depth, scar width, pain, closure time, and total cost of closure. Adverse events were similar. They concluded that based on the wound healing process, the cosmetic outcomes exhibited a favorable inclination toward CTAs at 1 to ≤3 months. Subsequently, sutures exhibited superior cosmetic outcomes compared to CTAs at >3 to 12 months.

Musham A, Samuel EMK, Sahoo AK et al (2023)[42] conducted a single-blinded randomised controlled trial to compare the skin closure time, postoperative pain and the scar outcome between tissue adhesive and sub-cuticular sutures in thyroid surgery. A total sample of 124 patients were included in this study, with 61 patients assigned to the suture group and 63 assigned to the tissue adhesive group. The results indicated that the median skin closure time and postoperative pain was significantly lower in the tissue adhesive group as compared to the suture group. There was no statistically significant difference in scar outcome at the 1st or 3rd months between both groups. There were no wound-related complications in either group. When a subgroup analysis was conducted, no difference was seen in the scar outcome or wound-related complications in patients with comorbidities. There were no instances of allergic contact dermatitis to the tissue adhesive. They finally concluded that the use of tissue adhesive leads to lower operative time and less postoperative pain in thyroid surgeries. The scar outcome is comparable between tissue adhesives and subcuticular sutures.

MATERIALS & METHOD

MATERIALS

The study was conducted in the Department of Oral and Maxillofacial Surgery, Santosh Dental College and Hospitals, Ghaziabad and allied private hospitals.

STUDY DESIGN:

The study was a randomised control study, group allocation was done randomly using online random sequence generation. This study was carried out over the duration of two years. A detailed case history was obtained and a thorough clinical examination was done. Preoperative assessment of existing lacerations and intraoperative incisions was done which included the length of laceration/incision. Patients were explained about the surgical procedure, its complications and the follow-up period involved in the study.

ETHICAL CONSIDERATION:

Ethical approval was taken from the Institutional Ethical Committee (IEC), Santosh Deemed to be University, Ghaziabad, Delhi- NCR, ensuring all procedures adhered to ethical standards. Each participant was informed about the usage of "SubQ It!" subcuticular dermal stapler and a written informed consent was obtained from them before enrolment (Annexure 6). Detailed information about study purpose, procedures, potential risks and benefits were also explained to the participants. Participants were assured of their right to withdraw from the study at anytime without any repurcussions.

SAMPLE SIZE:

Based on study design and statistician inputs a total of 18 patients (9 patients in each group) were recruited for the study who required either extra oral incisions intraoperatively subsequent to major maxillofacial surgical procedures or repair of deep lacerated wounds in the maxillofacial region for a period of 18 months (February 2023 – November 2024)

After ensuring the eligibility of study subjects, the subjects were assigned to two study groups as planned. The subjects were informed about the sequence of procedure in detail. This group allocation was done randomly using online random sequence generation.

Group I: Test group ("SubQ It!" subcuticular dermal stapler)

Group II: Control group (3-0 vicryl suture)

SELECTION CRITERIA

INCLUSION CRITERIA –

- Patients who were willing to provide written consent.
- Patients within the age group of 18 to 80 years.
- Patients who required extra oral incisions in the head and neck measuring upto 5 cm in length and 1 cm in depth
- Patients who required repair of deep lacerated wounds in the head and neck region
- Patients in ASA category I and II
- Patients willing to report for follow up were included.

EXCLUSION CRITERIA –

- Any patient not fulfilling inclusion criteria were excluded.
- Patients with immunosuppressive diseases (Medically compromised patients)
- Patients with previous history of irradiation
- Wounds from animal or human bites.
- Decubitus ulcers & crush injuries.
- Known allergy to poly-glactin and poly-lactic acid
- Patients with diabetes mellitus.
- Known personal or family history of keloid formation or scar hypertrophy.
- Patients who refused to provide written informed consent
- Patients who refused to provide written informed consent (Annexure 3)

The subjects were recruited as per the eligibility criteria after getting the informed consent.

ARMAMENTARIUM

Group I – Test group (SubQ It!)

- Disposable hypodermic syringes.
- Surgical scalpel
- Fine Adson's tissue folding forceps
- Skin hooks

- Cotton roll
- Dry gauze
- SubQ It! stapler (Fig-1.1)

Fig.1.1 : SubQ It! Stapler

The "SubQ It!" (OPUS KSD) fastener is 5.3 mm long and weighs 0.006 grams. It is moulded from a polyglycolic/polylactic acid copolymer, a well established material for resorbable medical devices. Fasteners maintain 80% of their strength for 21 days to support healing and then degrades by hydrolysis and are absorbed by normal physiological processes in subsequent months. The "SubQ It!" disposable stapler system is preloaded with ten (10) bioabsorbable fasteners and has the ability to deploy its fasteners into small 5-15mm incisions as well as longer incisions.

Group II – Control group (3-0 vicryl)

- 3-0 Vicryl suture (Fig-1.2)
- Surgical scalpel
- Tweezers
- Cotton roll
- Adson's tissue holding forceps
- Mosquito forceps
- Dry gauze

- Skin hooks
- Mayo suture cutting scissors
- Needle holding forceps

Fig.1.2 : 3-0 Vicryl Suture

METHOD

A detailed case history and thorough clinical examination supported by radiographic and hematologic assessment was done as per the case history proforma.

- Patients with extra oral incisions intraoperatively subsequent to major surgical procedures or repair of deep lacerated wounds were admitted and posted for surgery under LA/GA after routine blood investigations and pre-anesthetic evaluation. Extraoral and intraoral preparation was done with betadine and standard aseptic draping protocol were followed. The area of surgery was exposed extraorally using an appropriate approach. The surgical procedure was performed as per the treatment plan. Closure of the deep tissues was done in layers after debridement using 3-0 vicryl. Closure of the dermis and hypodermis was done using bioabsorbable subcuticular dermal stapler (SubQ It!) in order to achieve hemostasis in group I while in group II dermis and hypodermis closure was done using 3-0 vicryl followed by skin closure using prolene.

In group I

- The SubQ It! Stapler was applied carefully, in a stepwise approach to ensure proper placement and secured fastening of dermal tissue. First, using sterile technique, the SubQ It!

Stapler was carefully removed from its foil pouch. The safety lock was disengaged by a twisting and pulling motion to prepare the device for use. Next, the assistant used adson forceps to grasp the dermal tissue, gently pulling it back approximately 3-4 mm from the edges of the wound ensuring an adequate working area for stapler placement.

- The surgeon then brought the forceps together to elevate the thin tissue, allowing it to slide between the stapler's feet. The assistant used the base of the stapler handle to advance it into the proper position, ensuring that the tissue was correctly situated. Once the stapler was in position, the surgeon held the forceps at a 45-degree angle, pressing the tips securely into the forceps locators. The assistant held the stapler in place, allowing the surgeon to feel pressure against the forceps locators. This step ensured that the tissue was taut and properly aligned, avoiding any folding or slack in the tissue (Fig 2.1).

- With the tissue held firmly, the surgeon resisted any slippage while the assistant deployed the stapler fasteners. The assistant pressed the plunger down in a smooth, deliberate motion until it reached its stopping point, securing the tissue in place (Fig 2.2). Following this, the surgeon grasped the tissue immediately in front of the stapler's feet, ensuring an 8-10 mm spacing between fasteners. The assistant kept the stapler in position until the surgeon grasped the next bite of tissue. The stapler was then slid forward and lifted, repeating the process.

- This careful coordination between the surgeon and assistant ensured precise stapler placement, optimal tissue tension, and proper fastener spacing, contributing to effective wound closure giving a dimpling effect (Fig. 2.3).

Fig. 2.1 : Depicting proper alignment of tissues with stapler feet

Fig. 2.2 : Depicting the surgeon resisting any slippage while the assistant deployed the stapler fasteners

Fig. 2.3 : Arrow depicting the dimpling of correctly secured tissues

In group II

- Closure of the deep tissues was done in layers after debridement using 3-0 vicryl. The 3-0 vicryl suture was carefully removed from its sterile packaging using sterile technique to maintain a contamination-free environment. The surgeon then identified the tissue layers to be closed and ensured that the wound edges were approximated. The surgeon held the 3-0 vicryl suture onto the needle holder while confirming the needle is securely positioned. The assistant gently manipulated the wound edges using adson's forceps to expose the muscle layer and ensure the tissue remains under slight tension for a smooth suture placement.

- The surgeon then introduced the needle at one end of the muscle layer, typically 3-4 mm from the wound edges. The surgeon passed the needle through the muscle tissue, ensuring the suture bites are deep and consistent, providing secure closure, meanwhile the assistant maintained tension on the suture while the surgeon continued to place the sutures at regular intervals, typically 3-5 mm apart. Once the opposite end of the muscle layer was reached, the suture was tied using a surgeon's knot to ensure stability and strength. The surgeon tightened the knot to avoid excessive tension on the muscle tissue. The assistant ensured proper tissue alignment during knot tying to avoid any gaps in the closure. Lastly the surgeon inspected the closure for any tension or irregularities and proceeded for the skin closure using 4-0 prolene suture. Eversion of the wound edges was ensured to distribute the wound tension more evenly and to prevent the formation of a depressed or concave scar.

- Intra-operative assessment was done according to the annexure 4 to record the length of incision/laceration (in mm), no. of staples deployed/no. of knots placed, no. of staples wasted and time taken for the closure of incision/laceration (in minutes)

PARAMETER	OBSERVED VALUE	
	GROUP I (SubQ It! stapler)	GROUP II (Vicryl)
1. Length of incision/laceration (in mm)		
2. No. of staples deployed/ No. of knots placed		
3. No. of staples wasted		
4. Time taken for the closure of incision (in minutes)		

The length of incision/laceration was recorded prior to starting closure using a sterile scale, the measurement was recorded in milimeters in both the groups. In group I the time of closure was recorded from onset of use of SubQIt at one end of the incision/laceration uptill the deployment of the last staple at the other end of the same. However in group II the time of closure was recorded at the onset of subcuticular layer closure using 3-0 vicryl from one end of the incision/laceration to the other. The time duration was recorded using a stopwatch and was measured in terms of minutes. During the course of deployment, no. staples wasted (unsuccessful attempts) were also recorded along with the no. of staples deployed successfully.

- Post-operative evaluation was carried out as per the annexure 5A, 5B, 5C at regular intervals on the third, seventh, fifteenth post-operative days, followed by one month and three months. The following parameters were evaluated

I. Objective evaluation of the efficacy of bioabsorbable subcuticular dermal stapler was done using ease of handling proforma by the surgeon (Annexure 5A)

This proforma was assessed by the surgeon performing the surgery, based on various parameters -

S. no.	Parameter	Rating based on functional quality				
		SubQIt stapler/3-0 vicryl				
		Excellent (4)	Good (3)	Fair (2)	Poor (1)	Very poor (0)
1.	Ease of positioning along the incision line					
2.	Time efficiency of closure					
3.	Incision approximation					
4.	Operator safety					

The rating of each group was recorded in order to assess the efficiency and learning curve of both SubQIt stapler and 3-0 vicryl suture.

II. Evaluation of healing of the incision sites was done clinically by Stony Brooks scar evaluation system as well as by studying standardized clinical photographs of the patient's incision site to assess for any discrepancy such as pigmentation, swelling and discharge (Annexure 5B)

SCAR CATEGORY	SCORE	Postoperative group I/group II				
		3rd Day	7th Day	15th Day	1 month	3 months
• WIDTH						
>2 mm	0					
< 2 mm	1					
• HEIGHT						
Elevated or depressed in comparison to surrounding skin	0					

Flat	1					
• COLOUR						
Darker than surrounding skin (red, purple, brown or black)	0					
Same colour or lighter than surrounding skin	1					
• HATCH MARKS/SUTURE MARKS						
Present	0					
Absent	1					
• OVERALL APPEARANCE						
Poor	0					
Good	1					

The maximum total score was marked as 5 and minimum total score was marked as 0

Mean scar score	**Interpretation**
0-0.4	Worst
0.5-1.4	Poor
1.5-2.4	Satisfactory
2.5-3.4	Fair
3.5-4.4	Good
4.5-5	Best

III. Evaluation of the post-operative wound dehiscence was evaluated by the Sandy Grading System for surgical wound dehiscence (Annexure 5C)

Grade	Description	Postoperative group I/group II				
		3rd Day	7th Day	15th Day	1 month	3 months
I	• Minor separation of the opposed incisional margins at any point along the incision, <2 mm depth. • No visible subcutaneous layer • No clinical signs and symptoms of infection					
Ia	• As above with clinical signs and symptoms of infection					
II	• Medium (single or multiple) separations of the opposed incisional margins to expose subcutaneous layer, >5 mm depth. • Bridging or tunneling of dehiscence evident					
IIa	• As above with clinical signs and symptoms of infection					
III	• Major (single or multiple) separations of the incisional margins to expose subcutaneous, fascial/muscle/tendons/organs					
IIIa	• As above with clinical signs and symptoms of infection					

STATISTICAL ANALYSIS

MS-Office Excel was used to organise the data and statistical analysis was performed. Statistical Package for the Social Sciences version 20 (SPSS version 20) was used to analyse the data. Fisher's exact test is a statistical test used to determine if there are non-random associations between two categorical variables when at least one expected frequency in a four fold table is less than five, the Fisher's Exact test is more appropriate than the Chi-square test. The test assesses the probability of the cell frequencies, given the marginal frequencies. The Fisher's exact test was used for soft tissue analysis. The Independent Samples t Test was used for hard tissue analysis which compares the means of two independent groups in order to determine whether there is statistical evidence that the associated population means are significantly different. One type of parametric test was the Independent Samples t Test.

REPRESENTATIVE CASE : GROUP I – SubQ It ! Stapler

Fig. 3.1 : Intraoperative incision site for Gillies temporal approach

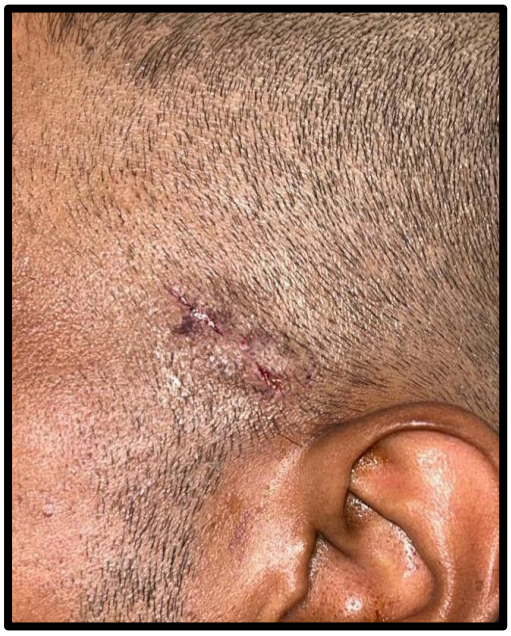


Fig. 3.2 : Immediate postoperative image after closure

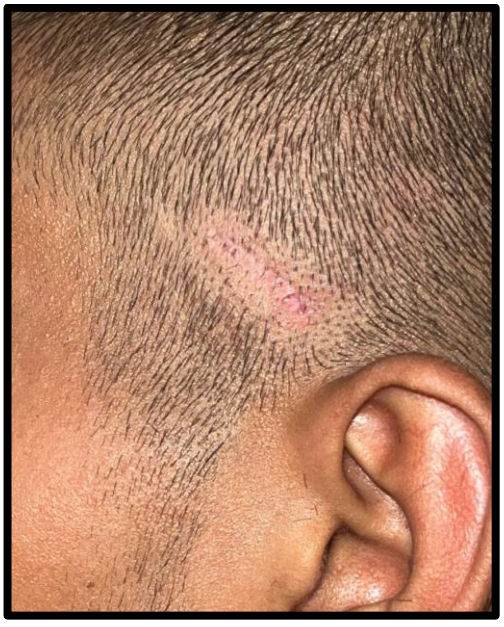


Fig. 3.3 : Postoperative day 15

Fig. 3.4 : Postoperative 1 month

Fig. 3.5 : Postoperative 3 months

REPRESENTATIVE CASE : GROUP II – Vicryl Suture

Fig. 4.1 : Preoperative laceration

Fig. 4.2 : Immediate postoperative image after suturing

Fig.4.3 : Postoperative day 15

Fig. 4.4 : Postoperative 1 month

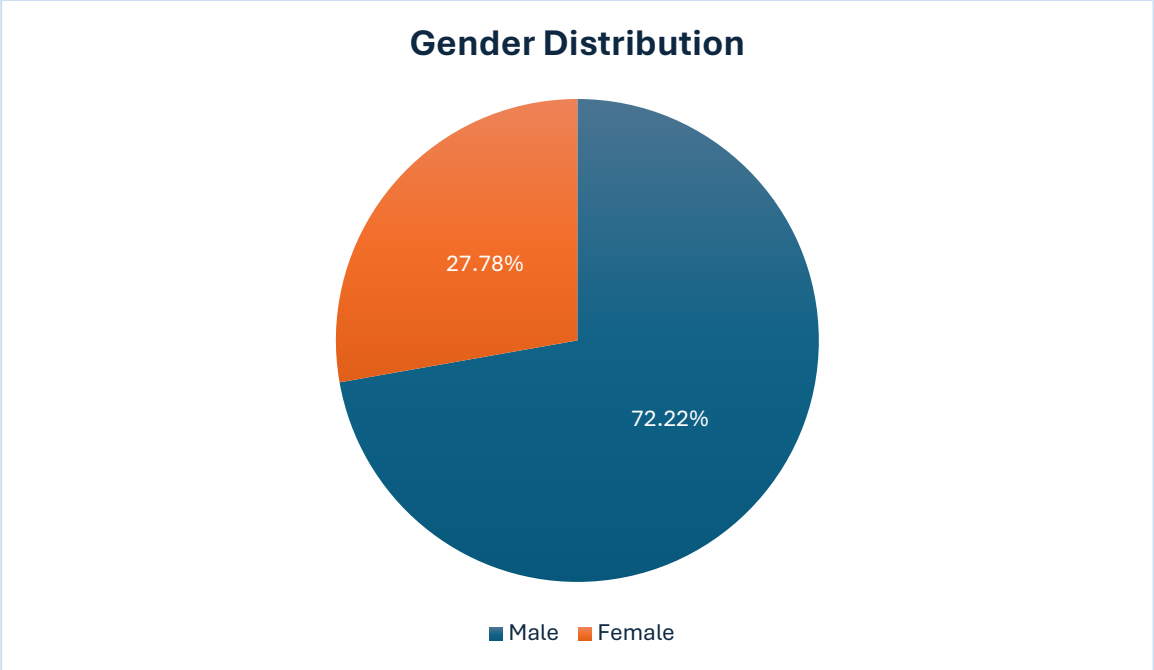
Fig. 4.5 : Postoperative 3 months

RESULT

A total of 18 patients with extraoral lacerations/incisions were included in this comparative study. 27.78% of the total population were females and 72.22% were males. The mean age of was 30.5 years for total population, 30.22 years for group I and 30.88 years for group II. The existing extraoral lacerations and incisions were closed with SubQIt stapler and 3-0 vicryl suture randomly.

Gender	Number	Percentage
Male	13	27.78%
Female	5	72.22%
Total	**18**	**100%**

Table 1: Gender distribution of patients included in the study



Graph 1: Pie chart depicting gender distribution in this study

Among the 18 patients analysed, the distribution of closure sites varied between Group I and Group II.

In Group I, the most common closure sites were the submandibular region, temporal region, and lateral brow region, each with 2 patients, accounting for 33.33%. These were followed by the forehead region, preauricular region, and malar region, each with 1 patient, contributing to 16.67%.

In Group II, the temporal region was the most frequently observed closure site, with 2 patients, representing 11.11% of the group. Other closure sites included the lateral brow region, forehead region, malar region, submental region, parasymphysis region, symphysis region, and retromandibular region, each with 1 patient, collectively accounting for 38.89%.

Sites of closure	Group I	Group II
Submandibular region	2 (11.11%)	
Temporal region	2 (11.11%)	2 (11.11%)
Lateral brow region	2 (11.11%)	1 (5.56%)
Forehead region	1 (5.56%)	1(5.56%)
Preauricular region	1 (5.56%)	
Malar region	1 (5.56%)	1 (5.56%)
Submental region		1 (5.56%)
Parasymphysis region		1 (5.56%)
Symphysis regions		1 (5.56%)
Retromandibular region		1 (5.56%)
TOTAL	9 (50%)	9 (50%)
	18 (100%)	

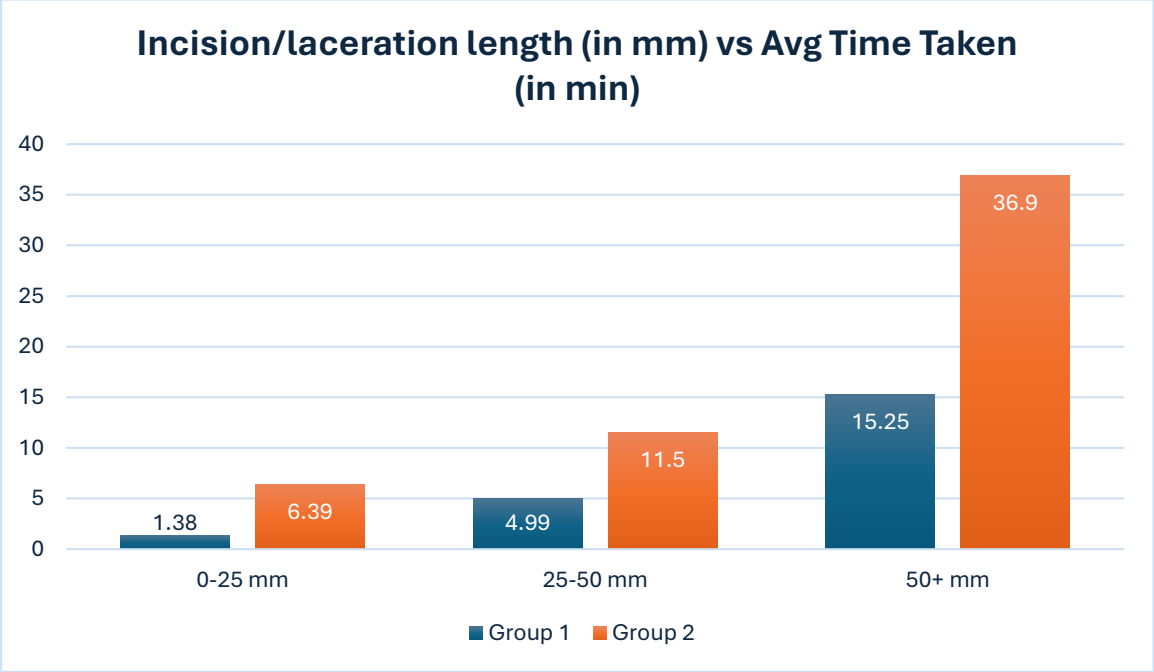
Table 2: Site of closure distribution among group I and group II

Interpretation: Overall data analysis revealed that submandibular region, temporal region and lateral brow region were the most common sites of closure constituting 44.44% of total patients.

Intra-operatively wound closure time was assessed and compared between group I and group II using stopwatch. Group I results revealed a significantly lesser time for closure of the wound as compared with group II. The mean length of incision/laceration in group I was 37.98 mm ranging from 65 to 20 mm which took a mean time of 5.67 min. for closure ranging from 22 to 1.2 min. The mean length of incision/laceration in group II was 59.66 mm ranging from 156 to 21 mm which took a mean time of 18.85 min. for closure ranging from 45.29 to 5.57 min.

	Mean length of incision/laceration	**Range of incision/laceration length**	**Mean time taken for closure**	**Range of time taken for closure**
Group I	37.98 mm	65 - 20 mm	5.67 min.	22 - 1.2 min
Group II	59.66 mm	156 - 21 mm	18.85 min	45.29 - 5.57 min.

Table 3: Comparison of mean time taken for closure between group I and group II



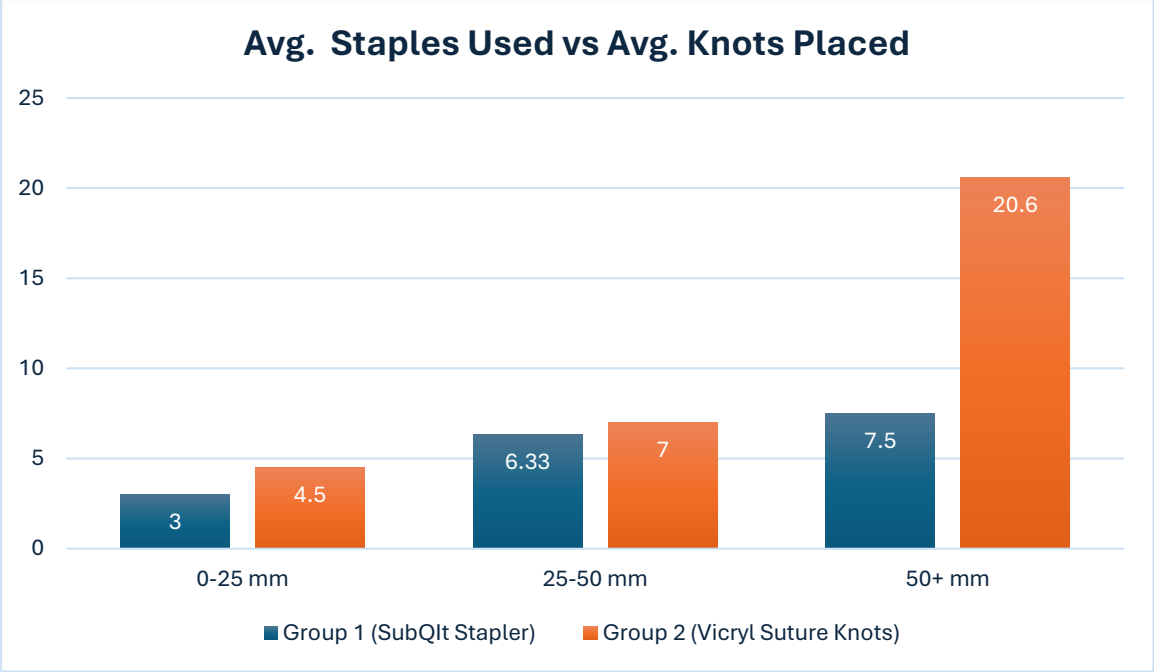
Graph 2: Comparison of average incision/laceration length and average time taken for closure between group I and group II

Interpretation: Group I demonstrated a significantly shorter wound closure time compared to Group II.

Intra-operatively no. of staples deployed and no. of knots placed were compared. Group I results revealed that lesser no. of staples were deployed for closure of the wound in comparison group II where more no. of knots were placed. In group I for an average length of 37.98 mm incision/laceration, the average no. of staples deployed were 5.11 ranging from 8 to 3 in no. while average no. of staples wasted were 1.22 ranging from 4 to 0 in no. However, in group II for an average length of 59.66 mm incision/laceration, the average no. of knots placed were 10.57 ranging from 29 to 4 in no.

	Mean length of incision/laceration	**Range of incision/laceration length**	**Mean no. of staples deployed/knots placed**	**Range of no. of staples deployed/knots placed**
Group I	37.98 mm	65 - 20 mm	5.11	8 - 3
Group II	59.66 mm	156 - 21 mm	10.57	29 - 4

Table 4: Comparison of number of staples deployed / knots placed between group I and group II



Graph 3: Comparison of average number of staples deployed / knots placed between group I and group II

Interpretation: Staple-based closure in Group I was associated with a lower material requirement, whereas Vicryl suture-based closure in Group II required a higher number of knots

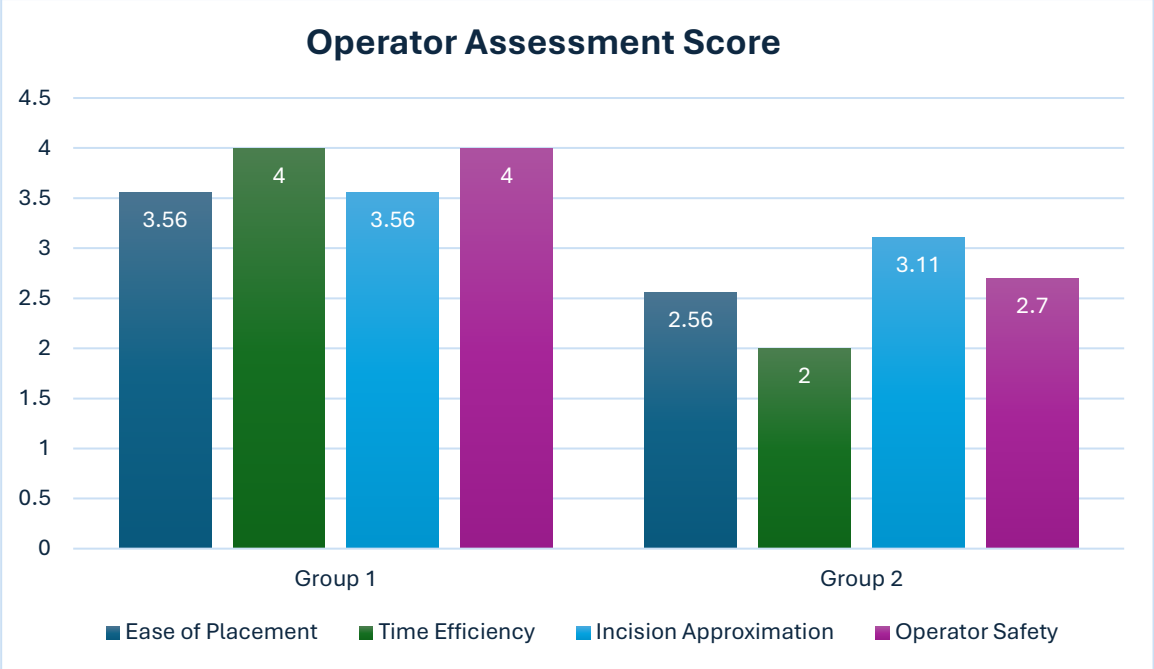
Intraoperatively, the operator assessed the functionality of the SubQIt stapler and Vicryl sutures by assigning scores based on various parameters. The results indicate that the SubQIt stapler demonstrated superior performance across all assessed criteria compared to Vicryl sutures.

In Group I, the operator assigned the highest possible score of 4 to the SubQIt stapler for all patients regarding time efficiency and operator safety, indicating optimal performance in these aspects.

In Group II, where Vicryl sutures were used, the operator assigned generally lower scores across all parameters. Among these, the lowest scores were observed for time efficiency and operator safety, suggesting that Vicryl sutures were comparatively less efficient and posed greater challenges for the operator.

	Parameters of assessment			
	Ease of placement	Time efficiency	Incision approximation	Operator safety
Group I	3.56	4	3.56	4
Group II	2.56	2	3.11	2.7

Table 5: Comparison of operator assessment scores between group I and group II



Graph 4: Comparison of operator assessment scores between group I and group II

Interpretation: SubQIt stapler was significantly more favorable in terms of usability, efficiency, and safety, while Vicryl sutures were associated with longer procedure times and increased operator difficulty.

Scar Evaluation

Comparison of scar score between Group I and Group II on postoperative day 3

In our study**,** scar score was compared between group I and group II using Stony Brook's scar Evaluation Scale.

Scar width - In both the groups two patients had a scar width > 2mm and 7 patients had a scar width < 2mm.

Scar height - In group I, out of 9 patients, 5 patients had an elevated scar and 4 patients had a flat scar. In group II, out of 9 patients, 8 patients had an elevated scar and only 1 patient had a flat scar

Scar colour - In group I, out of 9 patients, 4 patients had a scar colour darker than surrounding skin and 5 patients had a scar colour same colour or lighter than surrounding skin. In group II all the 9 patients had a scar colour darker than surrounding skin.

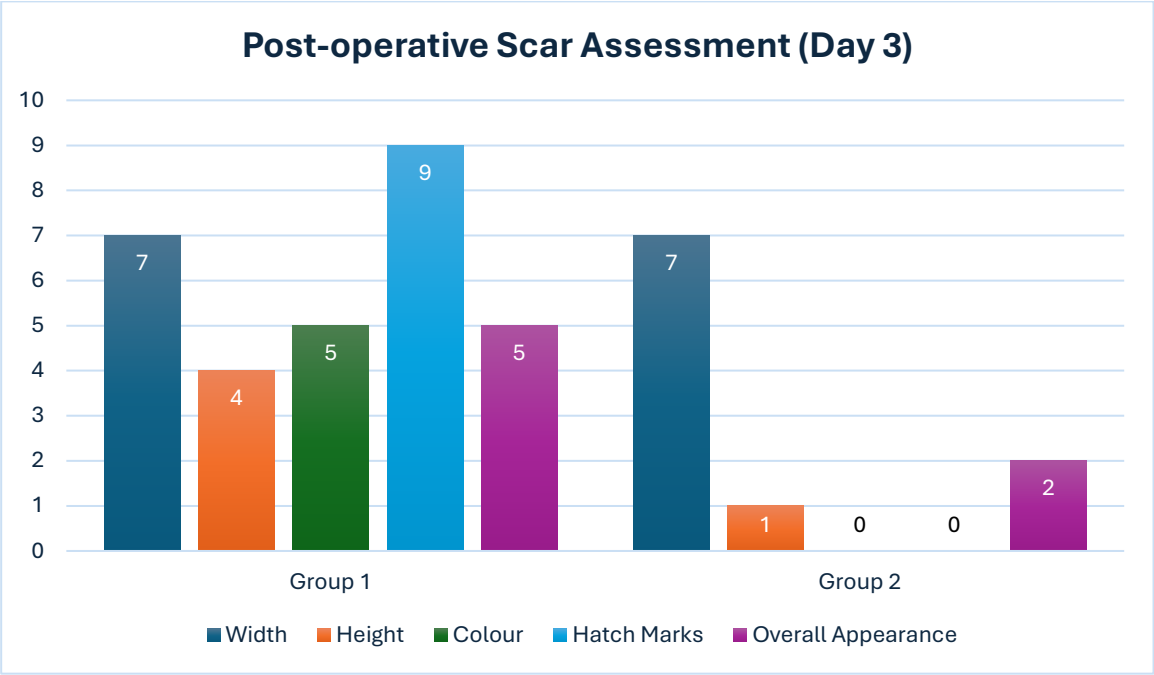
Hatch marks - In group I, none of the 9 patients had hatch marks. In group II, all the 9 patients, had hatch marks.

Overall scar appearance – In group I, out of 9 patients, 5 patients had a good overall scar appearance and 4 patients had poor overall scar appearance. In group II, out of 9 patients, only 2 patients had good overall scar appearance and 7 patients had poor overall scar appearance.

Parameters with a score of (1)	**Group I**	**Group II**	**Chi-square value**	**p value**
Scar width	7	7	9.4	< 0.1
Scar height	4	1		
Scar colour	5	0		
Hatch marks	9	0		
Overall scar appearance	4	2		

Table 6: Association of scar score between Group 1 & Group 2 at postoperative day 3

Interpretation: **Association of scar score at postoperative day 3 between two groups was not found statistically significant. Chi-Square value 9.4 & p value < 0.1.**



Graph 5: Comparison of postoperative day 3 scar scores between group I and group II

Comparison of scar score between Group I and Group II on Day 7

Scar width - In group I, all 9 patients, had a scar width < 2mm. In group II, out of 9 patients, 2 patients had a scar width > 2mm and 7 patients had a scar width < 2mm.

Scar height - All 9 patients in both the groups had 6 patients with an elevated scar and 3 patients with a flat scar

Scar colour - In group I, out of 9 patients, 2 patients had a scar colour darker than surrounding skin and 7 patients had a scar colour same colour or lighter than surrounding skin. In group II, out of 9 patients, 3 patients had a scar colour darker than surrounding skin and 6 patients had a scar colour same colour or lighter than surrounding skin.

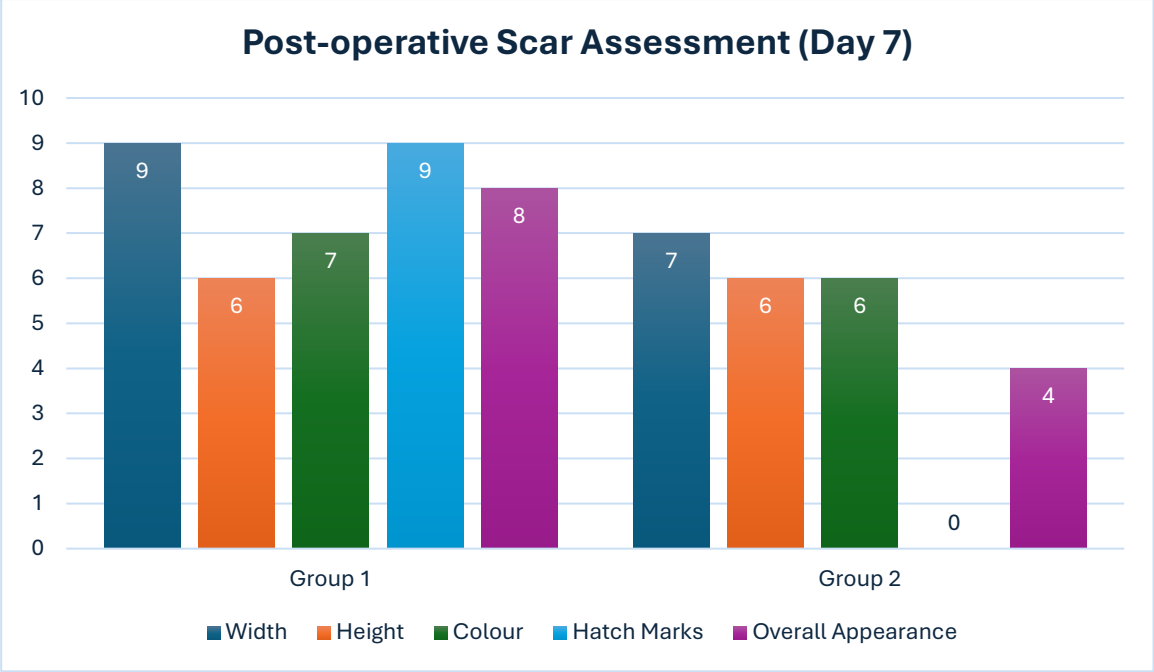
Hatch marks - In group I, none of the 9 patients had hatch marks. In group II, all the 9 patients, had hatch marks.

Overall scar appearance – In group I, out of 9 patients, 8 patients had a good overall scar appearance and only 1 patient had a poor overall scar appearance. In group II, out of 9 patients, only 4 patients had good overall scar appearance and 5 patients had poor overall scar appearance.

Parameters with a score of (1)	**Group I**	**Group II**	**Chi-square value**	**p value**
Scar width	9	7	13.83	< 0.025
Scar height	6	6		
Scar colour	7	6		
Hatch marks	9	0		
Overall scar appearance	8	4		

Table 7: Association of scar score between Group 1 & Group 2 at postoperative day 7

Interpretation: Association of scar score at postoperative day 7 between two groups was found statistically significant. Chi-Square value 13.83 & p value < 0.025.



Graph 6: Comparison of postoperative day 7 scar scores between group I and group II

Comparison of scar score between Group I and Group II on Day 15

Scar width - In group I, all 9 patients, had a scar width < 2mm. In group II, out of 9 patients, 2 patients had a scar width > 2mm and 7 patients had a scar width < 2mm.

Scar height - In group I, out of 9 patients, 2 patients had an elevated scar and 7 patients had a flat scar. In group II, all 9 patients had a flat scar.

Scar colour - All 9 patients in both the groups had a scar colour same colour or lighter than surrounding skin

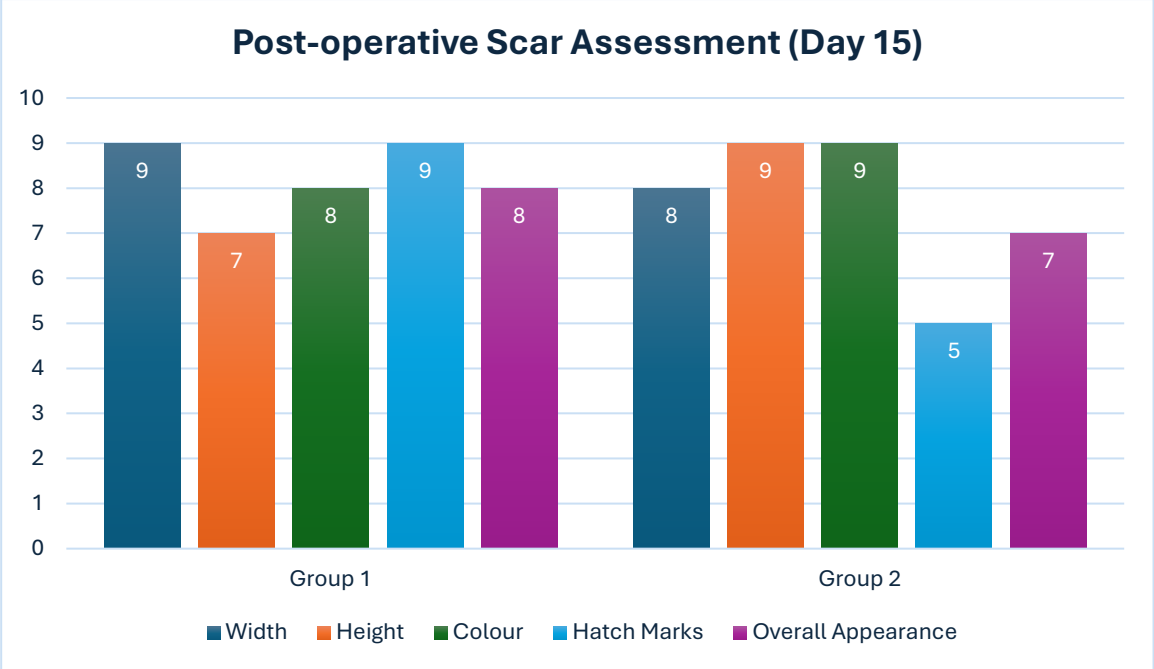
Hatch marks - In group I, none of the 9 patients had hatch marks. In group II, out of 9 patients, 4 patients had hatch marks.

Overall scar appearance – In group I, out of 9 patients, 8 patients had a good overall scar appearance and only 1 patient had a poor overall scar appearance. In group II, out of 9 patients, 7 patients had good overall scar appearance and 2 patients had poor overall scar appearance.

Parameters with a score of (1)	**Group I**	**Group II**	**Chi-square value**	**p value**
Scar width	9	8	3.025	< 0.7
Scar height	7	9		
Scar colour	8	9		
Hatch marks	9	5		
Overall scar appearance	8	7		

Table 8: Association of scar score between Group 1 & Group 2 at postoperative day 15

Interpretation: Association of scar score at postoperative day 15 between two groups was not found statistically significant. Chi-Square value 3.025 & p value < 0.7.



Graph 7: Comparison of postoperative day 15 scar scores between group I and group II

Comparison of scar score between Group I and Group II on Day 30 and Day 90

Scar width - In group I and group II, all the patients, had a scar width < 2mm.

Scar height - In group I and group II, all the patients, had a flat scar.

Scar colour - All 9 patients in both the groups had a scar colour same colour or lighter than surrounding skin

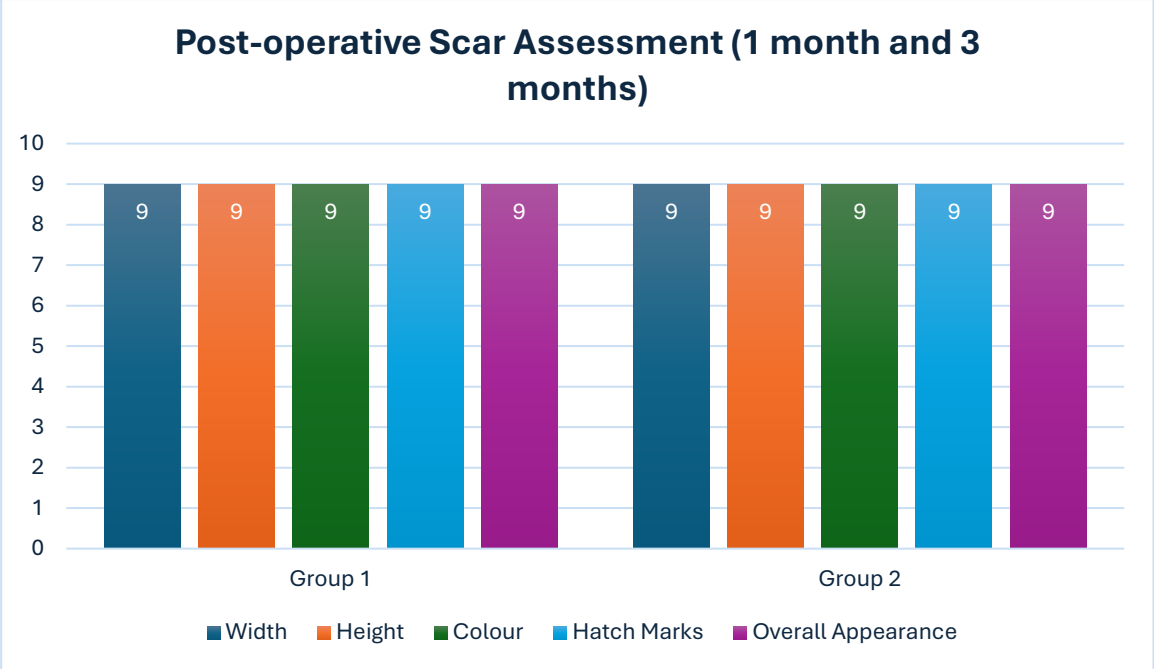
Hatch marks - In group I and group II, all the patients, had n hatch marks.

Overall scar appearance – In group I and group II, all the patients, had a good overall scar appearance.

Parameters with a score of (1)	**Group I**	**Group II**	**Chi-square value**	**p value**
Scar width	9	9	0	= 1
Scar height	9	9		
Scar colour	9	9		
Hatch marks	9	9		
Overall scar appearance	9	9		

Table 9: Association of scar score between Group 1 & Group 2 at postoperative day 30 and 90

Interpretation: Association of scar score at postoperative 1 month and 3 months between two groups was not found statistically significant. Chi-Square value 0 & p value=1.



Graph 8: Comparison of postoperative 1 month and 3 months scar scores between group I and group II

Comparison of mean scar score between Group I and Group II on Day 3, Day 7, Day 15, 1 Month and 3 Months

In our study**,** scar score was compared between group I and group II using Stony Brook's scar Evaluation Scale and the score interpretation table.

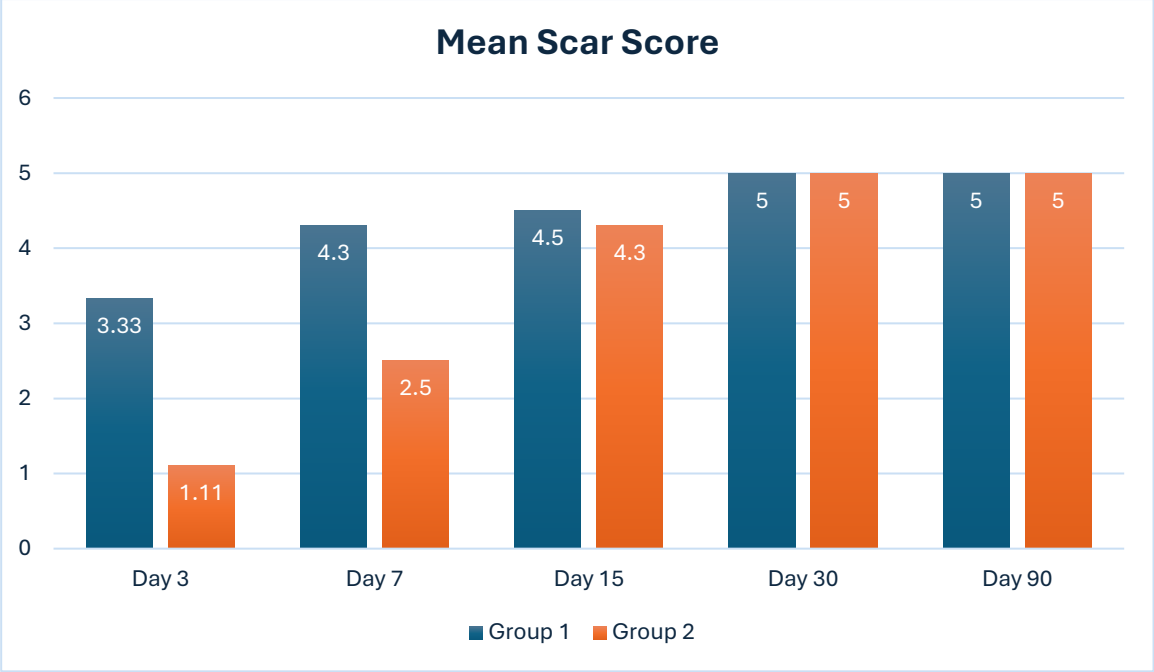
The results indicated that there was a significant difference between the mean scar score scores on postoperative day 3 and day 7. Since postoperative day 15 both the groups showed similar scar scores.

Post operative follow-ups	**Group I**	**Scar score interpretation – group I**	**Group II**	**Scar score interpretation – group II**
Day 3	3.33	Fair	1.11	Poor
Day 7	4.3	Good	2.5	Fair
Day 15	4.5	Best	4.3	Good
1 Month	5	Best	5	Best
3 Months	5	Best	5	Best

Table 10: Comparison of mean scar score between Group 1 & Group 2 at all postoperative follow up visits.

Mean scar score	**Interpretation**
0-0.4	Worst
0.5-1.4	Poor
1.5-2.4	Satisfactory
2.5-3.4	Fair
3.5-4.4	Good
4.5-5	Best

Interpretation: Group I patients had a better scar than the group II patients on all postoperative follow up visits.



Graph 9: Comparison of mean scar scores between group I and group II at all postoperative follow up visits.

Sandy grading system for surgical wound dehiscence was used for the assessment of wound dehiscence but no cases of wound dehiscence were observed in either of the groups in this study.

DISCUSSION

The earliest recorded use of sutures comes from ancient Egypt (3000 BCE), where linen threads and animal sinew were used to stitch wounds. At around 600 BCE ancient Indian physicians, such as Sushruta, described surgical techniques involving sutures in the *Sushruta Samhita*. They also used natural materials like plant fibers and even live ants (which bit the wound together before their bodies were removed, leaving their jaws as clamps). Later in the medieval and renaissance period (500 CE – 1700s) the use of gut sutures became more widespread in Islamic and European medicine. Surgeons experimented with various materials like horsehair, silver wire, and catgut. It was not until 1870s when a scientist named Joseph Lister introduced antiseptic techniques, leading to sterilization of sutures, which significantly reduced infections. By the late 19th century, mass production of sterilized silk and catgut sutures improved surgical outcomes. Introduction of synthetic sutures such as nylon, polyester, and polypropylene took place at around 1920s-1930s. In 1960s development of absorbable synthetic sutures (e.g., polyglycolic acid, polylactic acid), reduced the need for suture removal. Late 20th century marked advancement in suture coatings, antibacterial sutures, and biodegradable options[42].

Natural suture materials are those derived from biological sources, typically from animal tissues or plant fibers, and have been traditionally employed in surgical practice. One of the most commonly used suture was catgut. It is produced from purified collagen extracted from the intestines of sheep or cattle. It is an absorbable suture material, gradually degraded by enzymatic activity within the body. However, its absorption rate can be unpredictable, leading to variability in wound support. Additionally, catgut is known to provoke a relatively intense inflammatory response, which may compromise healing and predispose the wound to infection[43]. Silk sutures on the other hand are derived from the fibers produced by silkworms and are classified as non-absorbable. They are valued for their excellent handling characteristics and knot security. Despite these advantages, silk sutures have a multifilament structure that can harbor bacteria, thereby increasing the risk of infection. Furthermore, silk may induce a pronounced tissue reaction, contributing to inflammation and potentially delaying the healing process[44].

Cotton and linen were also employed as suture materials. Although these plant-based fibers are biocompatible, they generally offer inferior tensile strength and are prone to degradation in the moist environment of a healing wound. Their physical properties are inconsistent, and they elicit a more pronounced tissue reaction compared to modern materials, limiting their reliability and

effectiveness in surgical applications[14]. While natural suture materials played a pivotal role in the evolution of surgical techniques, their drawbacks—such as variability in absorption, heightened inflammatory responses, and susceptibility to bacterial colonization—have prompted the development and preference for synthetic suture materials in contemporary clinical practice.

Synthetic sutures offer several advantages over natural sutures, making them the preferred choice in modern surgical practice. One of the primary benefits is their predictable absorption and degradation. Unlike natural absorbable sutures such as catgut, which degrade enzymatically and can vary in absorption rate depending on the patient's biological environment, synthetic absorbable sutures degrade through hydrolysis, ensuring a more controlled and consistent breakdown process. Additionally, synthetic sutures induce less tissue reaction and inflammation compared to natural sutures, particularly catgut and silk, which are known to provoke significant immune responses, leading to fibrosis and potential scarring. Another key advantage of synthetic sutures is their superior tensile strength and durability. They maintain their structural integrity for a more predictable duration, reducing the likelihood of premature suture failure. In contrast, natural sutures may lose their tensile strength unpredictably due to biological variability. Furthermore, synthetic sutures, particularly monofilament types such as polypropylene and polydioxanone, exhibit a lower risk of bacterial colonization, thereby reducing the likelihood of postoperative infections. Natural sutures, especially those with a braided structure like silk, create spaces where bacteria can accumulate, increasing the risk of infection. Moreover, synthetic sutures provide greater manufacturing consistency, as they are produced under controlled conditions to ensure uniformity in diameter, strength, and absorption characteristics. Natural sutures, derived from biological sources, may have inherent inconsistencies that affect their performance. Synthetic sutures generally offer better handling and knot security, as they are designed to have optimal flexibility and reduced fraying. Catgut, for example, is prone to fraying and breakage, which can compromise surgical outcomes. Finally, synthetic sutures are available in a wide range of specialized variants, including antibacterial-coated and prolonged-absorption types, providing surgeons with tailored options for specific medical applications. Given these advantages, synthetic sutures have largely replaced natural sutures in most surgical procedures, ensuring improved patient outcomes and reduced complications[5-8].

The development of new wound closure methods in head and neck surgeries has significantly improved surgical outcomes, reducing complications such as infection, scarring, and prolonged healing times. Surgical adhesives, particularly cyanoacrylate-based tissue glues, have become

widely utilized for closing small incisions and superficial wounds in facial and neck procedures. These adhesives create a strong, flexible barrier that protects the wound while promoting natural healing without the need for suture removal. They are especially beneficial in pediatric and cosmetic surgeries, where minimizing discomfort and achieving optimal aesthetic results are priorities[30]. Another advancement is the use of adhesive skin closure strips, such as reinforced Steri-Strips, which are applied externally to hold wound edges together. These strips reduce tissue trauma, eliminate the risk of track marks associated with sutures, and are particularly useful in delicate areas such as the eyelids and perioral region. Additionally, zip-type skin closure devices, which feature adjustable adhesive fasteners, provide precise tension control and improved cosmetic outcomes while minimizing the risk of dehiscence[45]. For deeper closures, barbed sutures, though technically still sutures, represent a significant innovation by eliminating the need for knot tying, thereby reducing operative time and improving tissue approximation.

In cases of reconstructive or oncologic surgeries, laser tissue welding has emerged as a promising technique, utilizing laser energy to bond tissue proteins at a microscopic level, thereby reducing inflammation and promoting seamless healing[46]. Furthermore**,** negative pressure wound therapy (NPWT**)** is increasingly employed for complex head and neck wounds, particularly in cases involving large defects or flap reconstructions, as it enhances vascularization, reduces edema, and accelerates tissue integration[47]. Despite these advancements lacunaes remain.

The SubQIt! subcuticular dermal stapler offers solution to most of the drawbacks observed in other wound closure methods. The bioabsorbable staples used in SubQIt! gradually hydrolize within the body, eliminating the need for removal and reducing patient discomfort. Since the staples are placed within the subcuticular layer, they do not puncture the epidermis, resulting in reduced surface trauma and superior cosmetic outcomes compared to traditional sutures and metallic staples. The automated stapling mechanism allows for rapid and consistent wound closure, significantly decreasing surgical time compared to conventional suturing techniques. Unlike braided sutures, which can harbor bacteria, the smooth bioabsorbable staples reduce the risk of bacterial colonization and post-operative infections. The design of the device ensures even tension across the wound, promoting optimal healing and reducing the risk of dehiscence or wound irregularities. The absence of external sutures or metal staples minimizes post-operative irritation and pain, contributing to a more comfortable recovery process. Since the staples are bioabsorbable, no follow-up procedure is required for removal, reducing the need for additional medical visits and associated costs. By securing the wound internally and preventing track marks

commonly associated with external staples or sutures, the SubQIt! system enhances aesthetic outcomes, making it particularly beneficial for head, neck, and cosmetic surgeries. The device is suitable for various surgical fields, including plastic surgery, dermatology, general surgery, and minimally invasive procedures, making it a versatile closure option[1-6].

The first and only study till date which used bioabsorbable subcuticular dermal stapler in the region of head and neck was done by Hari KM et al.[5] in 2021. The study consisted of 12 patients who underwent surgical procedures requiring extraoral incisions in head and neck region, 9 patients underwent neck dissection and 3 underwent submandibular incisions. Intraoperatively, the average length of incision closed was 192.08 mm taking average time of 2 min. 55 sec. for closure. Post-operatively, the scar was objectively assessed using Modified Vancouver scar scale for 6 months along with patient satisfaction. The scar assessment scores were found to be decreasing with every postoperative visit and 'P' value was statistically significant. They concluded that the absorbable subcuticular staples have the capacity to potentiate wound closure even in high tension regions, although it had to be reinforced by the subcutaneous sutures in such areas.

Our comparative study included a total of 18 patients presenting with extraoral lacerations or incisions, 4 closures were done in temporal region, 3 in lateral brow region, 2 in submandibular region, and 1 in the forehead region, preauricular region, malar region, submental region, parasymphysis region, symphysis region, and retromandibular region each (Table 2). Of the total study population, 27.78% were female, while 72.22% were male. The mean age of the participants was 30.5 years overall, with an average of 30.22 years in Group I and 30.88 years in group II (Table 1& Graph 1). The extraoral lacerations and incisions were closed using either the SubQIt! stapler or 3-0 Vicryl sutures, assigned randomly.

Cross KJ et al.[1] in 2009 conducted a prospective, randomised, controlled study to evaluate more cost effective method for incisional closure in patients undergoing bilateral breast reconstruction. Eleven patients (22 incisions) were enrolled in this study, comparison was done between standard suture and dermal stapler, wound assessment was done by a blinded plastic surgeon using the 13-point Vancouver Scar Scale. The average length of incision for both the groups was 13.32 cm & 13.50 cm respectively and the time closure being 3 min. 6 sec. & 14 min. 1 sec. respectively, concluding that dermal stapler provided 4 times faster closer than suture. Similar results were found in studies by Dresner HS et al.[2] and Duteille F et al.[3] On the contrary study by Feese CA

et al.[4] (2013) revealed that the time for skin closure was significantly different i.e 3 min. 5 sec. for absorbable and 1 min. 37 sec. for metallic staples (P < .0001).

Study by Hari KM et al.[5] revealed that for a mean incision length of 192.08 mm the average number of staples deployed were 23.83 whereas in the study performed by Cross KJ et al.[1], 15.6 was the average number of staples deployed for a 13.32 cm long incision. None of the studies recorded number of unsuccessful attempts or number of staples wasted.

In our study intra-operative wound closure time was assessed and compared between group I and group II using stopwatch. Group I results revealed a significantly lesser time for closure of the wound as compared with group II. The mean length of incision/laceration in group I was 37.98 mm ranging from 65 to 20 mm which took a mean time of 5.67 min. for closure ranging from 22 to 1.2 min. The mean length of incision/laceration in group II was 59.66 mm ranging from 156 to 21 mm which took a mean time of 18.85 min. for closure ranging from 45.29 to 5.57 min. (Table 3 & Graph 2)

Intra-operatively no. of staples deployed and no. of knots placed were compared. Group I results revealed that lesser no. of staples were deployed for closure of the wound in comparison group II where more no. of knots were placed. In group I for an average length of 37.98 mm incision/laceration, the average no. of staples deployed were 5.11 ranging from 8 to 3 in no. while average no. of staples wasted were 1.22 ranging from 4 to 0 in no. However, in group II for an average length of 59.66 mm incision/laceration, the average no. of knots placed were 10.57 ranging from 29 to 4 in no. (Table 4 & Graph 3)

A comparative study between absorbable subcuticular dermal stapler and absorbable suture was done by Duteille F et al.[3] in 2013 where they evaluated the use of absorbable subcuticular stapler for cosmetic procedures like abdominal dermolipectomy and in surgeries for breast hypertrophy, the results revealed that the cosmetic outcomes were satisfactory in both the groups while wound dehiscence was observed in 2 patients where the stapler was used in tension areas. Cross KJ et al.[1] & Dresner HS et al.[2] performed comparative study between absorbable subcuticular dermal staples and metal staples which revealed that the cosmetic outcomes were consistent and better in the absorbable staples group throughout the duration of followup period whereas the scars developed by metal staples had hatch marks in the early followup days giving poor cosmetic appearance. However, by the end 1year followup period scars from both the groups were similar in appearance.

In our study, scar score was compared between group I and group II on postoperative day 3, 7, 15, 1 month and 3 months using Stony Brook's Scar Evaluation Scale. The statistical analysis of scar scores between Group I and Group II at different postoperative time points revealed varying levels of significance. On postoperative day 3, no statistically significant difference was found between the groups (Chi-Square value = 9.4, $p < 0.1$), indicating similar scar outcomes at this early stage (Table 6 & Graph 5). However, by postoperative day 7, a statistically significant difference emerged (Chi-Square value = 13.83, $p < 0.025$), suggesting that differences in wound healing and scar formation became apparent at this point (Table 7 & Graph 6). By postoperative day 15, this difference was no longer statistically significant (Chi-Square value = 3.025, $p < 0.7$), implying that the initial variations in scar appearance diminished (Table 8 & Graph 7). Furthermore, at both the 1-month and 3-month postoperative assessments, no significant differences were observed (Chi-Square value = 0, $p = 1$), indicating that long-term scar outcomes were comparable between the two groups (Table 9 & Graph 8). These findings suggest that while a significant difference in scar formation was noted at day 7, both closure methods ultimately resulted in similar long-term scar appearances.

Duteille F et al.[3] assessed a much important parameter associated with the device and that was the facility of use and handling of the stapler, where 0 was - very difficult to handle & 5 was - very easy to handle. All operators considered the stapler to be easy to handle giving a mean score of 4.3. In 2022 Singhal S et al.[35] conducted a study to evaluate the learning curve of an absorbable subcuticular stapling device in plastic and reconstructive surgery. The study included sixty-six patients who underwent cosmetic procedure corresponding to 254 unique linear incisions. Subdermal closure was done either with interrupted 3-0 Monocryl sutures or with "Insorb" device. The results indicated a mild learning curve with the assistant's use of "Insorb". They finally concluded that in addition to improved speed, cost, outcome, and ergonomics, subdermal absorbable staples garner a faster learning curve than standard closure with 3-0 Monocryl.

In our study, the intraoperative assessment of the SubQIt! stapler and Vicryl sutures was conducted by the operator based on multiple performance parameters, including ease of placement, time efficiency, incision approximation, and operator safety. In Group I, where the SubQIt! stapler was utilized, the highest possible score of 4 was consistently assigned for time efficiency and operator safety, signifying optimal performance in these aspects. Additionally, the stapler received an average score of 3.56 for both ease of placement and incision approximation, further demonstrating its efficacy. Conversely, in Group II, where Vicryl sutures

were used, lower scores were recorded across all parameters. The lowest ratings were observed for time efficiency (2.0) and operator safety (2.7), suggesting that the use of Vicryl sutures resulted in prolonged procedural times and increased difficulty for the operator. The scores for ease of placement (2.56) and incision approximation (3.11), while slightly higher, still indicated inferior performance compared to the stapler (Table 5 & Graph 4). These findings suggested that the SubQIt! stapler provided a more efficient, safer, and easier wound closure method compared to Vicryl sutures, particularly in terms of time efficiency and operator comfort.

Incidences of wound dehiscence and surgical site infections (SSIs) were evaluated by Vierhout BP et al.[26] in 2017. They compared closure of the skin by means of absorbable stapler with a cohort of patients treated with intracutaneous sutures where primary outcome was assessment of number of SSI's and secondary outcome was assessment of other complications, duration of surgery and hospital length of stay. 6 patients underwent skin closure with absorbable staples, 4 of them had SSI. Of 38 patients treated with intracutaneous sutures 7 had SSI (risk difference: 0.48, 95% CI 0.09-0.88). However, duration of surgery (p=0.84) and length of stay (p=0.15) were similar. Adversely in 2005 Farkas G et al.[49] used absorbable subcuticular dermal staples for closure of distal end of pancreas in 90 patients. The results indicated that no complications were observed in any of the patients except one who developed pseudocyst 6 months after surgery. These findings clearly indicate that dehiscence and SSI occur in tension areas.

In our study the wound dehiscence parameter was assessed using Sandy grading system, none of the patient in either of the groups showed any dehiscence.

There is a paucity of research on use of bioabsorbable subcuticular dermal stapler in head and neck region, despite the literature's abundance of studies on this novel approach to wound closure in other surgical domain. Therefore, in order to contribute additional clinical data and widespread administration of these staplers, more clinical trials with larger sample sizes and longer follow up periods are required.

CONCLUSION

The use of a bioabsorbable subcuticular dermal stapler represents a significant advancement in wound closure techniques. This innovative approach facilitates efficient and consistent skin approximation, reducing operative time while enhancing cosmetic outcomes. Our study on limited number of patients requiring closure of extraoral head and neck incisions/lacerations suggested SubQIt! bioabsorabable subcuticular dermal stapler to be superior to the conventional suture. Our study supports the faster rate of closure using SubQIt! stapler than 3-0 Vicryl leading to reduced operative time along with operator safety. Given these benefits, this study arrived at the conclusion that SubQIt! stapler outperforms conventional sutures in several aspects such as wound closure time, prevention of operational hazards such as needle stick injury and cosmetic outcome. Further studies and long-term clinical evaluations will continue to refine its applications and optimize its integration in the domain of maxillofacial surgery.

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ANNEXURE 1

ETHICAL COMMITTEE CLEARANCE FORM

SANTOSH
Deemed to be University
(Established u/s 3 of the UGC Act, 1956)

F. No. SU/2023/2480[20] Dated: 26.09.2023

Subject: Grant of Ethical Clearance for Thesis Protocol Topic **"A RANDOMISED CONTROLLED STUDY TO COMPARE & EVALUATE EFFICACY OF BIOABSORBALE SUBCUTICULAR DERMAL STAPLER AND VICRYL FOR EXTRAORAL WOUND CLOSURE"**, submitted by **Dr. DEEKSHA BAGHEL,** MDS student of Batch 2022-2023, Department of **ORAL & MAXILLOFACIAL SURGERY.**

*****

With reference to his/her request for grant of Ethical Clearance for the Thesis Protocol entitled **A RANDOMISED CONTROLLED STUDY TO COMPARE & EVALUATE EFFICACY OF BIOABSORBALE SUBCUTICULAR DERMAL STAPLER AND VICRYL FOR EXTRAORAL WOUND CLOSURE", Dr. DEEKSHA BAGHEL** is informed that the Thesis Protocol submitted by him/her was considered by the **Screening Committee** of the Santosh Dental College & Hospital in its meetings held on 07.02.2023 & 08.02.2023. The recommendations of the **Screening Committee** were considered in detail by the Institutional **Ethics Committee** in its meeting held on **23.09.2023** and the same was **approved** by the **Ethics Committee.**

He /She is informed accordingly for further necessary action.

[DR. NARESH SHARMA]
REGISTRAR

SANTOSH DEEMED TO BE UNIVERSITY REGISTRAR GHAZIABAD, (U.P.)

Dr. DEEKSHA BAGHEL
MDS student of batch 2022-2023
Department of ORAL & MAXILLOFACIAL SURGERY
Email: vineebaghel@gmail.com

Copy to:
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2. The Dean, SDC&H
3. The Dean – Research
4. The Dean – Academics
5. The Director - IQAC
6. **Dr. Amit B Lall** (Guide)
7. HOD of **ORAL & MAXILLOFACIAL SURGERY**

ANNEXURE 2

ANTI-PLAGIARISM REPORT

Dr.Deekksha Baghel

A RANDOMISED CONTROLLED STUDY TO COMPARE & EVALUATE EFFICACY OF BIOABSORBABLE SUBCUTICULAR D...

Santosh University, Ghaziabad

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ANNEXURE 3

PATIENT PROFORMA

NAME:

AGE/SEX:

ADDRESS:

CHIEF COMPLAINT:

HOPI:

PAST MEDICAL HISTORY:

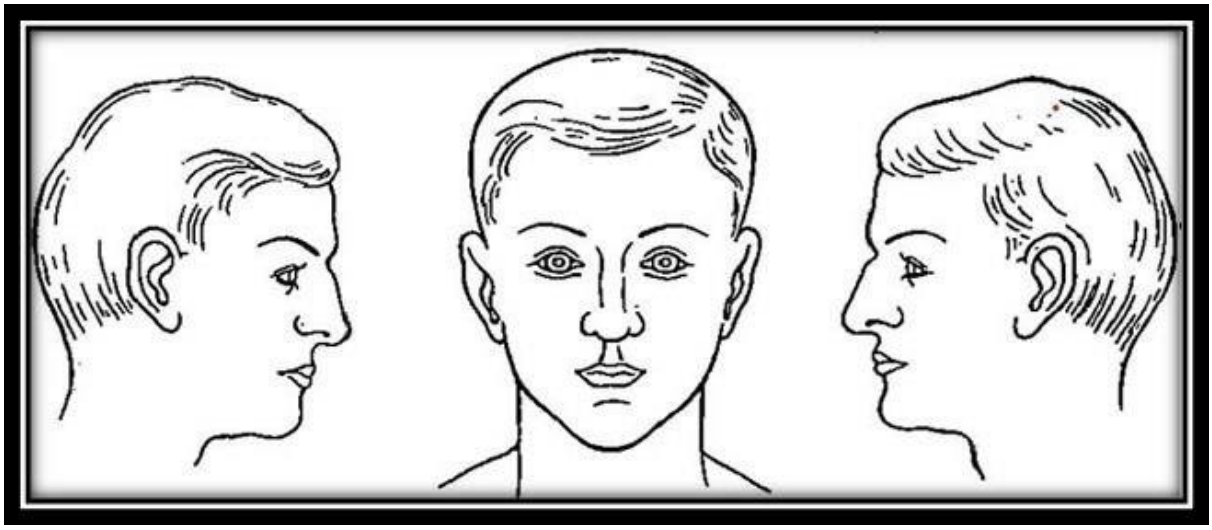
PAST DENTAL HISTORY:

HABITS:

GENERAL PHYSICAL EXAMINATION:

EXTRAORAL EXAMINATION:

Site of laceration-



Dimensions of laceration-

INTRAORAL EXAMINATION:

SOFT TISSUE:

Lips:

Labial and Buccal mucosa:

Palate:

Gingiva:

Floor of the mouth:

Tongue:

HARD TISSUE**:**

Teeth present:

Missing teeth:

Decayed:

Fractured:

PROVISIONAL DIAGNOSIS:

BLOOD INVESTIGATIONS:

RADIOGRAPHIC INVESTIGATIONS:

FINAL DIAGNOSIS:

TREATMENT PLAN:

ANNEXURE 4

INTRA OPERATIVE ASSESSMENT:

Date of the surgery:

PARAMETER	**OBSERVED VALUE**	
	GROUP I (SubQ It! stapler)	**GROUP II (Vicryl)**
1. Length of incision/laceration (in mm)		
2. No. of staples deployed/ No. of knots placed		
3. No. of staples wasted		
4. Time taken for the closure of incision (in minutes)		

ANNEXURE 5A

POST OPERATIVE ASSESSMENT:

S. no.	Parameter	Rating based on functional quality				
		SubQIt stapler/3-0 vicryl				
		Excellent (4)	Good (3)	Fair (2)	Poor (1)	Very poor (0)
1.	Ease of positioning along the incision line					
2.	Time efficiency of closure					
3.	Incision approximation					
4.	Operator safety					

ANNEXURE 5B

POST OPERATIVE ASSESSMENT:

Stony Brook's scar assessment scale

SCAR CATEGORY	SCORE	Postoperative group I/group II				
		3rd Day	7th Day	15th Day	1 month	3 months
• WIDTH						
>2 mm	0					
< 2 mm	1					
• HEIGHT						
Elevated or depressed in comparison to surrounding skin	0					
Flat	1					
• COLOUR						
Darker than surrounding skin (red, purple, brown or black)	0					
Same colour or lighter than surrounding skin	1					
• HATCH MARKS/SUTURE MARKS						
Present	0					
Absent	1					
• OVERALL APPEARANCE						
Poor	0					
Good	1					

ANNEXURE 5C

POST OPERATIVE WOUND DEHISCENCE ASSESSMENT:

Sandy Grading System

Grade	Description	Postoperative group I/group II				
		3rd Day	7th Day	15th Day	1 month	3 months
I	• Minor separation of the opposed incisional margins at any point along the incision, <2 mm depth. • No visible subcutaneous layer • No clinical signs and symptoms of infection					
Ia	• As above with clinical signs and symptoms of infection					
II	• Medium (single or multiple) separations of the opposed incisional margins to expose subcutaneous layer, >5 mm depth. • Bridging or tunneling of dehiscence evident					
IIa	• As above with clinical signs and symptoms of infection					
III	• Major (single or multiple) separations of the incisional margins to expose subcutaneous, fascial/muscle/tendons/organs					
IIIa	• As above with clinical signs and symptoms of infection					

ANNEXURE 6

INFORMED CONSENT

DEPARTMENT OF ORAL AND MAXILLOFACIAL SURGERY

SANTOSH DENTAL COLLEGE AND HOSPITAL, GHAZIABAD

"A RANDOMISED CONTROLLED STUDY TO COMPARE & EVALUATE EFFICACY OF BIOABSORBABLE SUBCUTICULAR DERMAL STAPLER AND VICRYL FOR EXTRAORAL WOUND CLOSURE"

I, Mr. / Ms ……..

S/O, D/O, W/O. ……..

Resident of ……
..

have been informed about all the benefits and risks during and after the surgical procedure. I am willingly participating in the study conducted by the department of Oral and Maxillofacial Surgery, Santosh Dental College and Hospital.

I should choose to withdraw from this study at any point; I will be free to do so after giving prior information to the concerned surgeon.

Signature of Surgeon In-charge

Date:

Signature of Patient

Date:

Signature of Parent/Guardian

Date:

शोध विषयस्वीकृति पत्र

मुह /जबड़ा शल्य चिकित्साविभाग

संतोष दंत महाविध्यालय एवं अस्पताल, गाजियाबाद

" बाहरी घाव को टाँके लगाने के लिए अवषेशीय चमड़ी के नीचे काम करने वाले स्टेपलर और विक्रिल की तुलना करने के लिए एक यादृच्छिक नियंत्रित अध्ययन"

मैं,श्री/श्रीमती/ .....

पुत्र/ पुत्र.....

निवासी.....

.....

.....

इस शल्य चिकित्सा के दौरान और उसके बाद होने वाले लाभ और जोखिम से भली- भाँति अवगत कराया गया हैं। मैं अपनी स्वेच्छा से मुँह व जबड़ा शल्यचिकित्सा विभाग, संतोष दंत महाविध्यालय एवं अस्पताल में आयोजित इस अध्ययन में अपना योगदान करना चाहती/चाहता हूँ। यदि मैं अध्ययन से किसी भी समय अलग होना चाहूँ तो चिकित्सक को सूचित करने के पश्चात अलग हो सकता/सकती हूँ।

....

चिकित्सक के हस्ताक्षर **मरीज के हस्ताक्षर.**

.....

संबंधी के हस्ताक्षर

ANNEXURE 7

MASTERCHART

INTRAOPERATIVE GROUP I (SubQIt - Bioabsorbable subcuticular dermal stapler) — **POSTOPERATIVE GROUP I (SubQIt - Bioabsorbable subcuticular dermal stapler)**

| | | | | | | | | | | | SCAR EVALUATION (STONY BROOK'S CRITERIA) | | | | | | | | | | | | | | | | | | | | | | SURGICAL WOUND DEHISCENCE (SANDY GRADING SYSTEM) | | | | | | | | | | | | | | | | | | |